GMDN User Guide

Version 2010

G•M•D•N

A comprehensive guide to the Global Medical Device Nomenclature

About this User Guide
The GMDN User Guide was written to help understand the purpose and function of the GMDN, how best to use the GMDN for its different purposes, how to use the GMDN Database to get the correct GMDN data, term and code selection and to provide advice on how to avoid using wrong or erroneous GMDN data.

Note: Examples of GMDN terms used in this User Guide are for demonstration purposes only and may not equate to actual GMDN terms.

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GMDN Agency
Services provided by the GMDN Agency are:

- GMDN guidance and information
- Development and access to GMDN terms and codes
- Development and access to Collective Terms
- GMDN membership and account services

The GMDN Agency website is at: www.gmdnagency.org

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1. Abbreviations

BSI	British Standards Institution
CD-ROM	compact disc read-only memory
CEN	Comité Européen de Normalisation / European Committee for Standardization
CNMD	Classification Names for Medical Devices and in Vitro Diagnostic Products
EC	European Commission
EDMA	European Diagnostic Manufacturers Association
EFTA	European Free Trade Association
EUDAMED	European Database for Medical Devices
EU	European Union
FDA	Food and Drug Administration
GMDN	Global Medical Device Nomenclature
ISO	International Organization for Standardization
ISO 9999	ISO 9999: Assistive products for persons with disability – Classification and terminology
NKKN	Norsk Klassifisering Koding & Nomenklatu*r,* Norwegian Nomenclature
PDA	Personal Digital Assistant
UMDNS	Universal Medical Device Nomenclature System

2. Background

Prior to the GMDN, many nomenclature systems existed, all built upon different structures, and used locally or nationally for different purposes and with different approaches. These different systems, though often workable in their own right, have had no impact on improving the overall situation of providing a common platform whereby medical devices could be correctly identified and the related data safely exchanged between the involved parties.

The advent of the European directives initiated a new era where national, and indeed international bodies, were given the opportunity to co-operate and harmonize their efforts in achieving the one thing that they all needed, namely, a standardized method of identifying the products placed upon the global market.

Work by the standards organizations CEN and ISO from 1993 to 1996 resulted in a standard that specified a structure for a new nomenclature for medical devices. This standard, revised by ISO, is published as *ISO 15225 Nomenclature – Medical device nomenclature data structure*. Following this, a project was set up in 1997 by CEN with financial support from the European Commission (EC). The aim of the project was to create a comprehensive nomenclature for all medical devices suitable for use by all interested parties globally.

To facilitate the rapid production of the GMDN six existing nomenclatures of particular standing were adopted. These covered a wide range of terms defining medical devices and healthcare products that combined gave a total of 13 500 terms.

The 6 chosen nomenclatures were:

CNMD	Classification Names for Medical Devices and in Vitro Diagnostic Products. Developed by Food and Drug Administration (FDA) USA.
EDMA	European Diagnostic Manufacturers Association in vitro diagnostic product classification. Used in Europe.
ISO 9999	Technical Aids for Disabled Persons Classification. International use.
JFMDA	Japanese Medical Device Nomenclature. Used by Japan.
NKKN	Norsk Klassifisering Koding & Nomenklatu*r,* Norwegian Nomenclature.
UMDNS	Universal Medical Device Nomenclature System. Developed by ECRI, USA.

On the 1st of November 2001 the Global Medical Device Nomenclature (GMDN) was published as a *CEN Report CR 14230* and as *ISO TS 20225.* The first public release on CD-ROM as GMDN version 2002.1 was in November 2002.

Within all regulations concerned with medical devices there are a number of obligations placed upon the manufacturer. In addition, the authorities are faced with the task of regulating manufacturers and their devices, and there are the people involved in trade with these devices, e.g., the suppliers, before the devices themselves are brought into use. Finally, of course, there is the myriad of users who, when the devices initially arrive at the place of intended use, struggle with the quite hopeless task of trying to correctly identify and register these devices in their local databases.

There are a number of players, having quite different responsibilities and levels of understanding of the processes, but all with the one common interest, that of ensuring the availability of sound medical devices to the general public. To assist in this very important process there is a need for a common method for describing and identifying these medical devices in an unambiguous manner.

The GMDN now provides, for the first time, an international tool for identifying all medical devices at the generic level in a meaningful manner that can be understood by all users.

In June 2010 ISO published the latest version of *ISO 15225 Nomenclature – Medical device nomenclature data structure.*

3. GMDN Agency

The need for a maintenance organization was identified and the structure approved within CEN.

Therefore, in order to manage the GMDN, a maintenance agency has been set up to form the necessary legal entity. This non-for-profit company, “GMDN Agency”, acting as the Maintenance Agency Secretariat (MAS) and functioning as the hub in the running and maintenance of the GMDN, provides services and information for access to the GMDN data through this present Internet site or other means.

To ensure continuing permanency of the GMDN, revenues are generated through the licensing and sale of GMDN Agency products, particularly the GMDN codes which a user must buy in order to view them, and services, in particular the creation of new GMDN terms requested by persons needing an applicable new term and code for their product. Also, some funding may be allocated by relevant global regulatory bodies or other parties.

Services provided by the GMDN Agency are:

- Access to the GMDN data file and codes through the GMDN Internet site through a licence agreement and/or by direct credit card purchase.
- A link from the GMDN database to the user’s in-house data system by a licence agreement and a purpose made software link.
- Application form for new terms or modification of existing terms/definition for the identification of the user’s product.
- Access to GMDN terminology and information.
- Guidance on how to use the GMDN.
- Assistance to find an applicable GMDN code for a product.
- Access to Collective terms.
- GMDN translation software tool.

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3.1 GMDN Copyright

The copyright of the electronic version of the GMDN is exclusively owned by the GMDN Agency Ltd who is authorized through the British Standards Institution (BSI) to be the sole Maintenance Agency and distributor of the electronic version of the GMDN.

Therefore, no part of the GMDN data file may be reproduced or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in any retrieval system of any nature, for use outside the GMDN Agency without the permission of the GMDN Agency.

The GMDN Agency also owns and exercises full copyright for other GMDN products which include:

- A unique database and search engine to facilitate public access to and maintenance of the GMDN data file.
- Compendium of dedicated terminology, glossary and relevant abbreviations.
- Auto correction facility and other spelling protocols.
- Dedicated Public Internet access site.
- Software in support of translation processes.

3.2 Disclaimer

The GMDN Agency is at all times working to create a best possible nomenclature containing descriptors for medical devices and related healthcare products at a generic level for the purpose of product identification. This provides a globally acceptable method so that related information can be utilised for a number of purposes. (It is the responsibility of the GMDN user to ensure that the appropriate term and code is applied when using the GMDN for product identification). The application of a GMDN descriptor (by way of the GMDN code) does not exempt the responsible person from any product approval requirements called for by legislation. Nor does the GMDN attempt to predefine when a generic device group is a medical device or not, this is entirely dependant on the regulating legislation. In no circumstances will the GMDN Agency be held liable for any direct, indirect, consequential or incidental damage, including loss of profits, business interruption, loss of data, incurred by the user through deficiencies, the inability to use the GMDN, or inaccurate information presented in the GMDN, regardless of presentation medium. It is the obligation of the user to ensure notification of dubious or incorrect product representation in the GMDN to the GMDN Agency in the case of dissent between the user and the GMDN.

Note: "Search terms/entry terms" may include proprietary names when these are commonly accepted and used by the health care profession. This does not in any way give reference to a specific make or manufacturer, and must never be used for product identification. When proprietary names are used in the GMDN, there is no implied accuracy to the correct representation of the name as used by the manufacturer/legal owner.

A manufacturer/legal owner may submit suggestions to amend or enter a proprietary name into the GMDN data file. All submissions for new terms will be considered by the GMDN Expert Team.

4. Purpose of the GMDN

The foremost purpose of the GMDN is provide a single, global, nomenclature system by which the authorities can regulate medical devices; this also impacting upon the health care providers, that are the mainstay users of medical devices, the medical device manufactures, suppliers, conformity assessment bodies and other affiliated parties, so that there is only one single system that provides the generic product descriptors to support patient safety.

The GMDN code represents the generic descriptor (this being the term name along with its definition) in order to internationally standardize device identification for reasons of safe data exchange between competent authorities and others, exchange of post-market vigilance information, research, medical record keeping, e-commerce, and inventory purposes.

Any authority, company, or user not using the GMDN will automatically exclude themselves from the above purpose.

4.1 Languages

The master copy of the GMDN data file (the nomenclature) is principally written in English. To accommodate North American English and when applicable, the American spelling has been adopted.

The GMDN has been translated to some languages, but most of this work is still in progress. In the meantime, the EU has embarked upon translation of the GMDN to the 20 standard languages of the European Union. The first phase of this work is due to be completed in 2010.

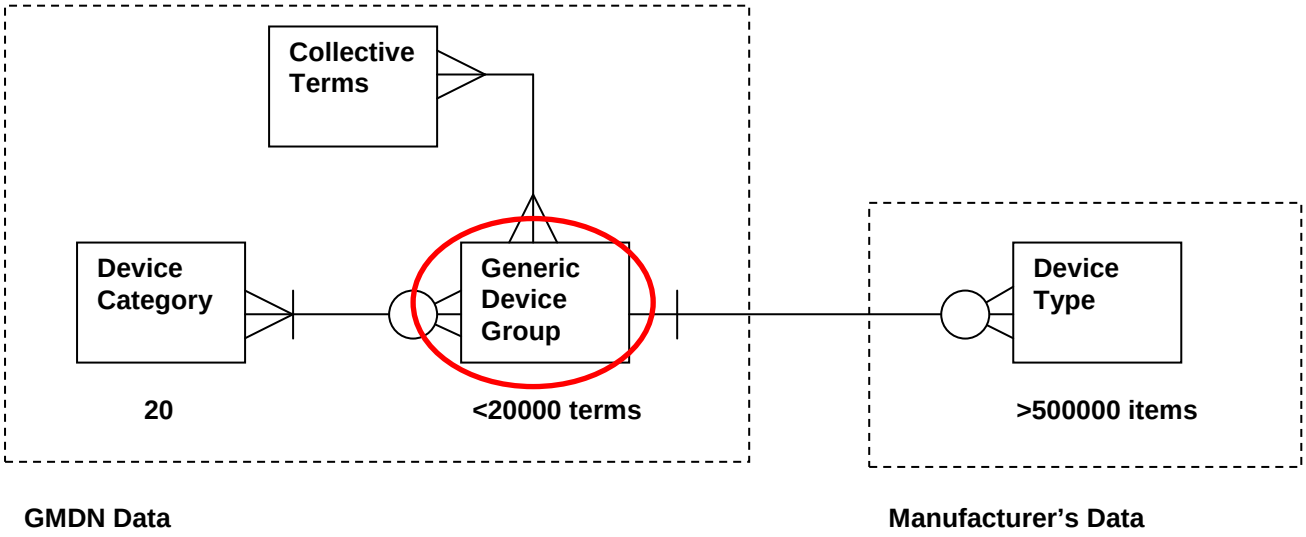
Translations will be made available in the GMDN web-based database once they are ready.

5. Structure

The general structure of the GMDN is regulated by requirements stipulated in the standard ISO 15225 *Nomenclature – Medical device nomenclature data structure*. This standard, together with this document, should provide the necessary understanding of the GMDN's features and utilization.

The figure below shows the basic organization of GMDN data. The data is defined by three levels, associated with an external fourth level, each level containing data that differs in degree of specificity.

The Generic Device Group is the GMDN Preferred Term.



5.1 Device Category

The device category is the broadest level of the GMDN data. It divides the entire medical device product market into highest-level groups based on device application, technology, or other common characteristics. The standard (ISO 15225) allocates codes for 20 categories. These are:

Category	Description
01	Active implantable devices
02	Anaesthetic and respiratory devices
03	Dental devices
04	Electro mechanical medical devices
05	Hospital hardware
06	In vitro diagnostic devices
07	Non-active implantable devices
08	Ophthalmic and optical devices
09	Reusable devices
10	Single use devices
11	Assistive products for persons with disability
12	Diagnostic and therapeutic radiation devices
13	Complementary therapy devices
14	Biological-derived devices
15	Healthcare facility products and adaptations
16	Laboratory equipment
17	Vacant
18	Vacant
19	Vacant
20	Vacant

5.2 Generic Device Group

The generic device group is the most specific level at which products are aggregated based on common technology or intended use. There are four different types of GMDN terms associated with the generic device groups. These terms, with their alpha identifiers, include:

Preferred term	P
Template term	T
Synonym term	S
Multiple-linked synonym term	MS

5.2.1 Preferred terms

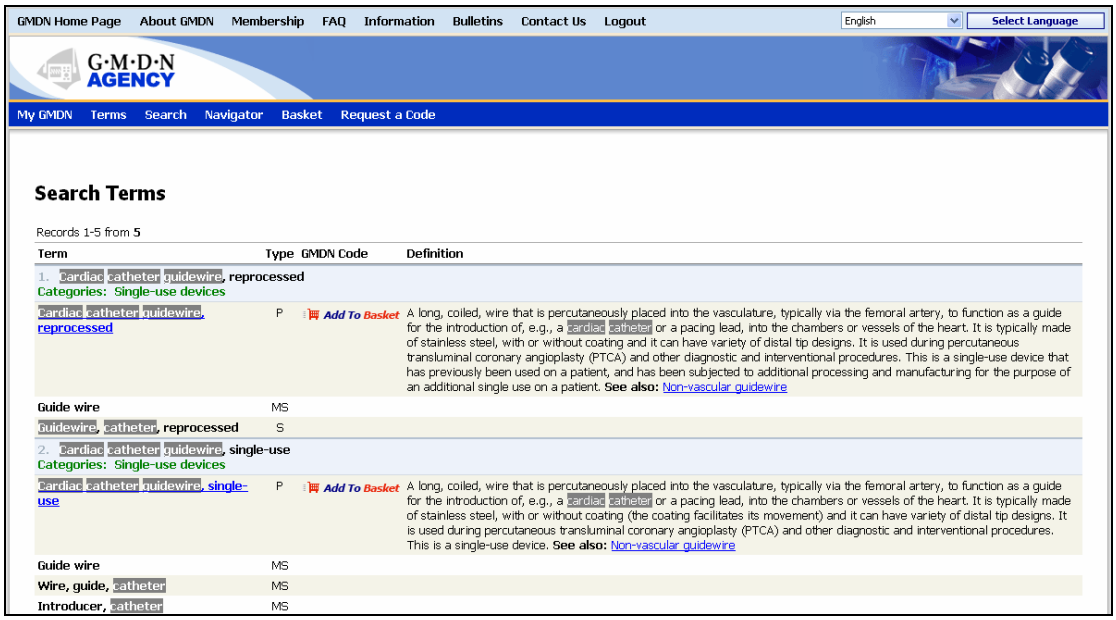
Preferred terms with their unique 5 digit codes are the only terms available for product identification. The preferred term is the optimal name selected to represent a group of devices (a collection of device types) that have the same or similar intended use or commonality of technology allowing them to be grouped in a generic manner, typically without reflecting specialized characteristics such as brand or trade names.

Each preferred term has an associated definition that describes the most prominent characteristics of the device types in the group [typically includes a physical description and an intended use(s)]. It is the definition that determines the scope of the preferred term and code.

The text, *Product Identifier* is associated with all active preferred terms to clearly show that these are the only terms valid for product identification.

EXAMPLE: preferred term showing product Identifier

From the *Search* page enter on the term of interest, for example Catheter Cardiac and Guidewire and this will list all the terms that contain these words.


GMDN Home Page
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Contact Us
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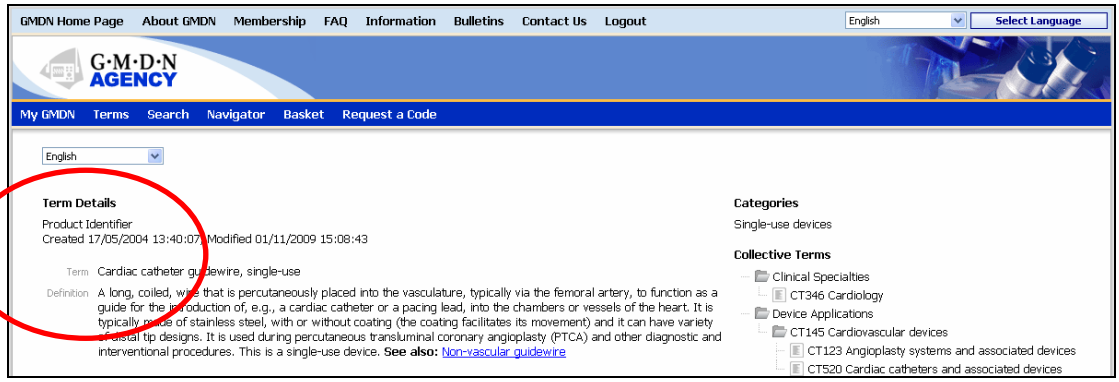
English
Select Language
G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
Search Terms
Records 1-5 from 5
Term
Type
GMDN Code
Definition
1. Cardiac catheter guidewire, reprocessed
Categories: Single-use devices
Cardiac catheter guidewire, reprocessed
P
Add To Basket
A long, coiled, wire that is percutaneously placed into the vasculature, typically via the femoral artery, to function as a guide for the introduction of, e.g., a cardiac catheter or a pacing lead, into the chambers or vessels of the heart. It is typically made of stainless steel, with or without coating and it can have variety of distal tip designs. It is used during percutaneous transluminal coronary angioplasty (PTCA) and other diagnostic and interventional procedures. This is a single-use device that has previously been used on a patient, and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. See also: Non-vascular guidewire
Guide wire
MS
Guidewire, catheter, reprocessed
S
2. Cardiac catheter guidewire, single-use
Categories: Single-use devices
Cardiac catheter guidewire, single-use
P
Add To Basket
A long, coiled, wire that is percutaneously placed into the vasculature, typically via the femoral artery, to function as a guide for the introduction of, e.g., a cardiac catheter or a pacing lead, into the chambers or vessels of the heart. It is typically made of stainless steel, with or without coating (the coating facilitates its movement) and it can have variety of distal tip designs. It is used during percutaneous transluminal coronary angioplasty (PTCA) and other diagnostic and interventional procedures. This is a single-use device. See also: Non-vascular guidewire
Guide wire
MS
Wire, guide, catheter
MS
Introducer, catheter
MS

Click on Cardiac catheter guidewire, single-use for the *Term Details*:


GMDN Home Page
About GMDN
Membership
FAQ
Information
Bulletins
Contact Us
Logout
English
Select Language
G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
English
Term Details
Product Identifier
Created 17/05/2004 13:40:07 Modified 01/11/2009 15:08:43
Term
Cardiac catheter guidewire, single-use
Definition
A long, coiled, wire that is percutaneously placed into the vasculature, typically via the femoral artery, to function as a guide for the introduction of, e.g., a cardiac catheter or a pacing lead, into the chambers or vessels of the heart. It is typically made of stainless steel, with or without coating (the coating facilitates its movement) and it can have variety of distal tip designs. It is used during percutaneous transluminal coronary angioplasty (PTCA) and other diagnostic and interventional procedures. This is a single-use device. See also: Non-vascular guidewire
Categories
Single-use devices
Collective Terms
Clinical Specialties
CT346 Cardiology
Device Applications
CT145 Cardiovascular devices
CT123 Angioplasty systems and associated devices
CT520 Cardiac catheters and associated devices

See the *Product Identifier* text displayed.

The preferred term consists of a base concept, the first and principal component of the term e.g., “Cardiac catheter”, which may be followed by one or more qualifiers, if appropriate, to increase the specificity of the term e.g., “Cardiac catheter, balloon, intra-aortic”. Or it can be constructed as a stand-

alone compound noun without the use of qualifiers e.g., Cardiac catheterization kit.

The preferred term is associated with each of the following:

CODE	A unique numerical five-digit number.
DEFINITION	A generic description of the scope of the term, which includes the intended use(s).
CATEGORY	The highest device level to which a preferred term has been linked. All preferred terms have at least one linked category.
TERM TYPE IDENTIFIER	A capital letter or letters to denote the term type. For a preferred term, it is (P).
PRODUCT SPECIFIER	A text (a data field) that is displayed in the Term Details to indicate the product identification status of a term. In the case of an active preferred term it is *Product Identifier*, indicating that the preferred term can be used and is valid for product identification (e.g. product registration with a regulating body).

The preferred term type identifier is (P).

5.2.2 Template terms

The template term is a general device name added to the nomenclature when many preferred terms have identical character strings forming the base concept, and functions as a header term to create a simple hierarchy for lexically-related preferred terms.

Each template term has an associated definition that is inclusive of all subordinated preferred terms.

The template term type identifier is (T).

Important Note: The template term is a navigational tool only and must NOT be used for product identification purposes.

The template term is formed from the common base concept followed by the qualifier “<specify>”, making it easily recognizable.

EXAMPLE

T Venous compression system garment, <specify>
P Venous compression system garment, multi-chamber, reusable
P Venous compression system garment, multi-chamber, single-use
P Venous compression system garment, single-chamber, reusable
P Venous compression system garment, single-chamber, single-use

Important Note: If a template term code has in the past been used to identify any products, this code has been wrongly applied and is not valid. A GMDN P term and code that is applicable to the product must be selected and assigned instead. If no current GMDN P terms are applicable, a Request for a new term to be created or an existing P term to be modified must be submitted.

5.2.3 Synonym terms

The synonym term is a common use or familiar name used in the nomenclature. It is an alternative entry point in the nomenclature used to locate the preferred term or template term to which it is linked. It may or may not actually be synonymous with the term to which it is linked.

The synonym term type identifier is (S).

Selecting a synonym term in the GMDN database will automatically produce its linked preferred or template term.

If clicked on and selected the S term Tube, capillary, will automatically bring up the P term Blood capillary tube.

Synonym terms do NOT have definitions.

Important Note: The synonym term is a navigational tool only and must NOT be used for product identification purposes.

Synonym terms commonly include hospital jargon commonly used for medical devices.

Note: Trade names, inventor names, proprietary names and transitory terms, if they are well recognized, may be used as synonym terms when considered beneficial for providing a search to find the preferred term.

5.2.4 Multiple-linked synonym term

The multiple-linked synonym term is a medical device name that is typically higher-order and is therefore linked to more than one preferred term.

The multiple-linked synonym term type identifier is (MS)

Important Note: This multiple-linked synonym term is a navigational tool only and must NOT be used for product identification purposes.

5.3 Collective terms

Collective terms are high-level device terms used to aggregate medical device groups that have common features within the GMDN. Collective terms may be device names (e.g., Stents, Catheters, Pacemakers) or device attributes (e.g., Electrophysiology, Absorbable, Home-use); the device name collective terms are especially used to create hierarchical constructs in the GMDN.

Whereas the GMDN is designed and was developed for regulatory data exchange in areas such as vigilance reporting and tracking of medical device safety, there is a need for a set of terms that are more refined than the GMDN category terms, yet broader than the GMDN generic device group terms, to be used in the application of the medical device directives and for other regulatory purposes; the use of collective terms satisfies this requirement.

Collective terms are intended to be used for a whole range of subject matters, such as:

- To illustrate the scope of certificates issued by Notified Bodies when assessing which groups, families or types of medical devices are covered within a manufacturer's quality system,
- To be used to identify the range of skills and general technological abilities for which a Notified Body has been approved, and is so appointed by the relevant Competent Authority,
- For the exchanges of information between Competent Authorities when general information on individual manufacturers capabilities is notified for inclusion in the European Database for Medical Devices (EUDAMED).

For ease of electronic transmission of data and code recognition, each collective term is assigned a four-digit incremental code with the prefix "CT" (Collective Term).

EXAMPLE:

CT162	Orthopaedic cement and associated devices
CT287	Clinical chemistry IVDs
CT1033	Electrical catheters

The collective terms are linked to the appropriate P terms within the GMDN data file and are an intrinsic part of the GMDN Navigator, providing organization and a principal search mechanism. See the section on the GMDN Navigator.

5.4 Unique Device Identification

Unique Device Identification (UDI) is being introduced by Medical Device Regulators to track individual medical device products through their lifetime of use. The advantages of UDI can be summarised as follows:

- Reduce device related medical errors
- Improve identification in adverse event reports

- More effective device recalls
- Facilitate electronic medical record systems
- Improve device purchasing and reduce costs
- Help reduce counterfeit devices
- Reduce the risk of device shortages during emergencies

In order for UDI to be implemented individual products need to be marked by using the appropriate technology, for example a bar code, RFID tag or alternative and that individual ID needs to be stored in a database. To fulfil some of the possible uses of the UDI, a ‘generic device group’ needs to be included in the product record. The GMDN code fulfils all the requirements of a generic device group.

6. Coding

All terms in the GMDN are assigned a unique code. This provides the security in cases of misunderstandings, language barriers, or discrepancies in data systems. The code is an incremental, sequential cardinal number comprising five digits starting from 10000. The codes in themselves are not created with an integral hierarchical structure and are simply unique numbers. The code are the carriers of the information to which it is linked and should always be used and referred to in any reference to the GMDN or data transaction.

6.1 Codes in the range of 1-9999

Codes in the range of 1-9999 are not represented in the GMDN. These, as stated in the standard, are exclusively reserved for assignment by any end user and may be used as desired in any user's local data system.

Note: It is important for users to understand that this range of codes should not be used for any kind of official purpose, e.g., as temporary codes, as national translated synonyms, or where the data is exchanged between users outside of the local data system. This will lead to ambiguity.

6.2 Codes in the range of 10000-30000

Codes in the range of 10000-30000 are represented in the GMDN and have been reserved exclusively to represent the original code used by the ECRI organization for their UMDNS terms that have been adopted for use in the GMDN. The intention being to provide the GMDN user with automatic mapping from the ECRI code representing the UMDNS term to the identical GMDN code now used to represent the GMDN term.

6.3 Codes above the range of 30000

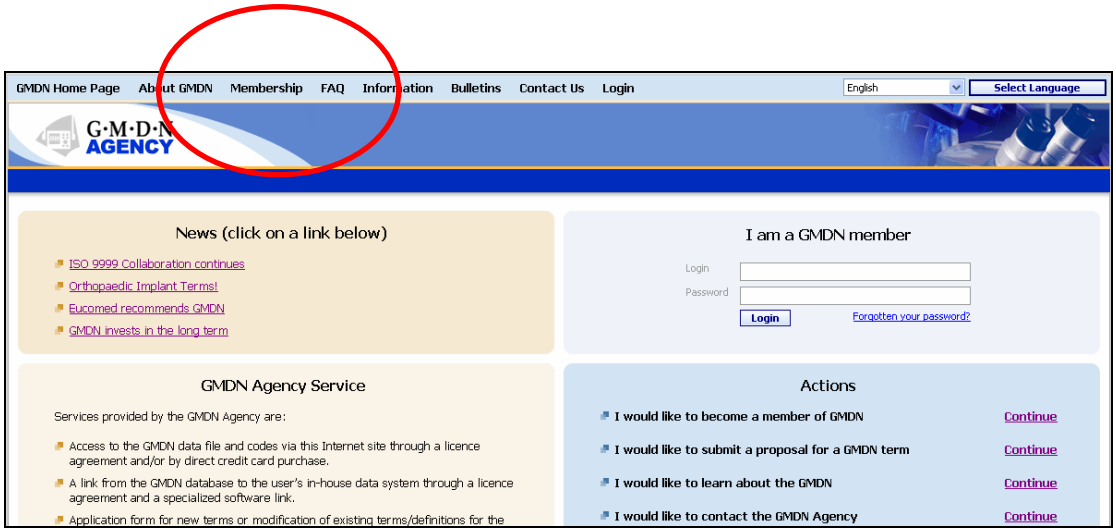
Codes above the range of 30000 are all GMDN produced `terms.

7. Access to the GMDN Data

The GMDN data, (i.e., the nomenclature, the codes, the categories and the collective terms with their links) and associated terminologies (i.e., GMDN glossary and abbreviations) are only available through the GMDN website.

This website will provide the user with real-time data only, and as the GMDN experts work and edit the GMDN, this data is made available through the GMDN website instantaneously. This provides the GMDN user, with the most recent data available. The user no longer has to wait for the release of a new version of the data, as one would if using CD-ROM or printed matter.

To access the GMDN, one must first become a GMDN member. This can be found at the URL www.gmdnagency.org that will bring up the GMDN Home page.


GMDN Home Page
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Information
Bulletins
Contact Us
Login
English
Select Language
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News (click on a link below)
ISO 9999 Collaboration continues
Orthopaedic Implant Terms!
Eucomed recommends GMDN
GMDN invests in the long term
I am a GMDN member
Login
Password
Login
Forgotten your password?
GMDN Agency Service
Services provided by the GMDN Agency are:
Access to the GMDN data file and codes via this Internet site through a licence agreement and/or by direct credit card purchase.
A link from the GMDN database to the user's in-house data system through a licence agreement and a specialized software link.
Application form for new terms or modification of existing terms/definitions for the
Actions
I would like to become a member of GMDN
Continue
I would like to submit a proposal for a GMDN term
Continue
I would like to learn about the GMDN
Continue
I would like to contact the GMDN Agency
Continue

Click on *Membership* on the top menu bar and select the membership schedule that is applicable.

The GMDN Agency also offers a service of creating a direct link from the GMDN database for automatic or manual download in accordance with a special negotiated license agreement. This provides the ability to import and use the GMDN data within a user's in-house data systems. To do this one must first obtain a special license issued by the GMDN Agency for incorporation of the GMDN data into a user software system. This allows a web service providing up to date information during the licence period.

Examples of such users are:

- Government bodies
- Large hospital organization
- Large manufacturers with a wide range of products
- Users of purpose-designed software systems containing GMDN data

Specific interfaces can be developed for clients by our GMDN technology partner Euro-Soft Developments Ltd.

7.1 Benefits of being a GMDN member

The benefits of being a GMDN member are:

- Access to the very latest information, there are no version releases – it is always real-time data.

- Access to the GMDN database from anywhere in the world; even through a personal digital assistant (PDA) or other electronic handheld information device.

- Customized selection and purchase of the number of GMDN codes. These will be stored in a personalized section of the GMDN called *My GMDN*. See section 7.4.

- Access to all of the GMDN terminologies and supporting files.

- Reduced renewal of membership and reduced new-term proposal costs.

- Access to the bulletins which provide current information on retired preferred terms that have been made obsolete (See section 11).

7.2 Use of old GMDN data and illegal websites

It is the absolute advice of the GMDN Agency not to use outdated GMDN data for identifying products and/or transmission of GMDN data. Because the FDA of the USA works together with the GMDN Agency to fully integrate and harmonize their Product Code (Procode) nomenclature system into the GMDN, with the intent of utilizing the GMDN for their Postmarked Surveillance Systems, there has been a continuing period of intense ongoing upgrading of the GMDN data file. This activity, of course, brings about many changes to the GMDN data file. The upside will, at the end of this updating process, be of massive advantage to the users, whereby products and registration records will, in the future, be recognized by the GMDN code.

This also means that the GMDN users must remain astute and not fall into the trap of using outdated data, which can be found on the Internet or old versions of GMDN on CD-ROM, or websites other than the official GMDN website, in order to obtain GMDN codes. Such methods could be extremely harmful to a business.

7.3 GMDN fees

The GMDN Agency is a non-for-profit organization. However, in order to maintain the GMDN, it must generate an annual income. This is done by charging for its services. These fees have been set to modest levels in proportion to the size of organisation, which is advantageous to GMDN members, bearing in mind the very specialized nature of the services provided.

7.3.1 Membership fees

Membership of GMDN is available to a range of users and is regulated by the following set of licenses:

Type	Applied to
A Membership	For Medical Devices National Regulatory Bodies
B Membership	For Manufacturers or Distributors of Medical Devices
C Membership	For Engineering Bodies dealing with Medical Devices and their Maintenance For Hospitals and Health Authorities using GMDN for inventory, purchasing, e-commerce
D Membership	For Conformity Assessment Bodies For Authorised Medical Device Inspectorates
E Membership	GMDN Agency Licence Agreements for links between the GMDN data-base and the Users of IT systems - negotiated facility arranged with GMDN Agency.
F Membership	GMDN Agency Licence Agreement with Translating Bodies Recognised by the Agency as appropriate translators for a given specific language version of GMDN.
G Membership	Special membership formulated for particular Medical Device Consultancy Organisations.
H Membership	Others.

Membership must be renewed annually (except where specifically excluded) to ensure continued access and search capability to the database. In most cases renewal costs are at a reduced rate from the initial joining fee.

7.3.2 Request for new or modified term fees

If an appropriate term when searched for is not found in the GMDN database or an existing GMDN term needs to be modified so that it can be applied to a product, users are encouraged to submit a GMDN Request. Because the

GMDN is a complex matrix of information, to create a new GMDN term and definition, or modify an existing term, the GMDN Agency does charge a fee to the applicant to cover some of the development cost.

Note 1: an extra term or terms will be created, upon assessment by the GMDN expert dealing with a Request, when this is deemed necessary to complete the wholeness of the GMDN data file resulting through the Request. For example, an applicant can apply for a device that is a system (a collection of several medical devices or system component devices that acting together fulfils the intended purpose of the system), then one P term for the entire system must be created and one P term for each of the devices the system consists of, including software. Or, in the case of a kit which contains devices that are also available to the market as individual devices as well as being part of that kit, the same logic applies, one P term for the entire kit must be created, and one P term for each of the devices packaged individually and available to the market that the kit consists of.

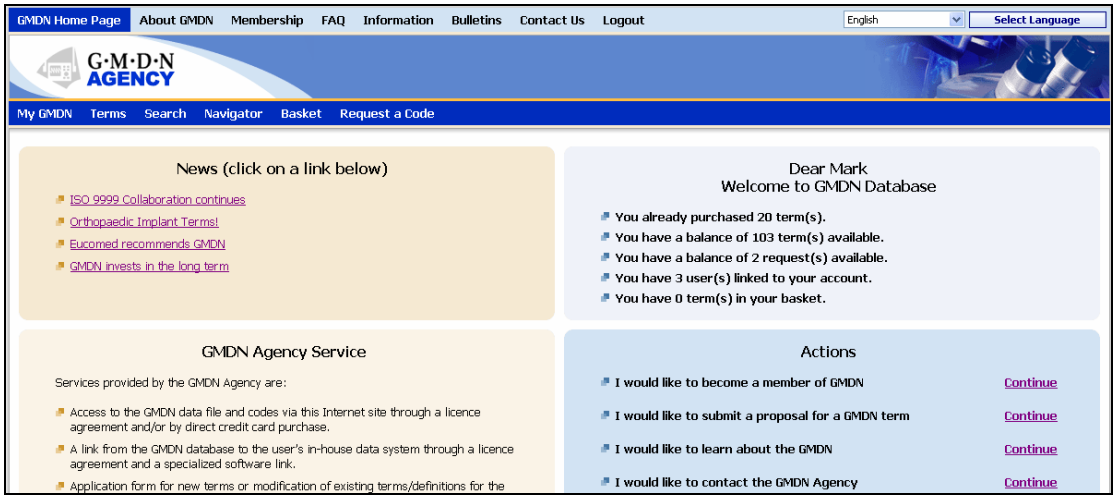
Note 2: the use of the above condition must not be prejudged by the applicant; this can only be applied by the GMDN expert dealing with the application, on behalf of the GMDN Agency.

7.3.3 Consultancy services

The GMDN Agency does reserve the right to charge a nominal fee when providing assistance to users who submit queries, especially in cases where the GMDN experts are involved and the query involves excessive usage of their time.

7.4 My GMDN

When GMDN member have logged in using a login name and password, they will enter the database via this view:

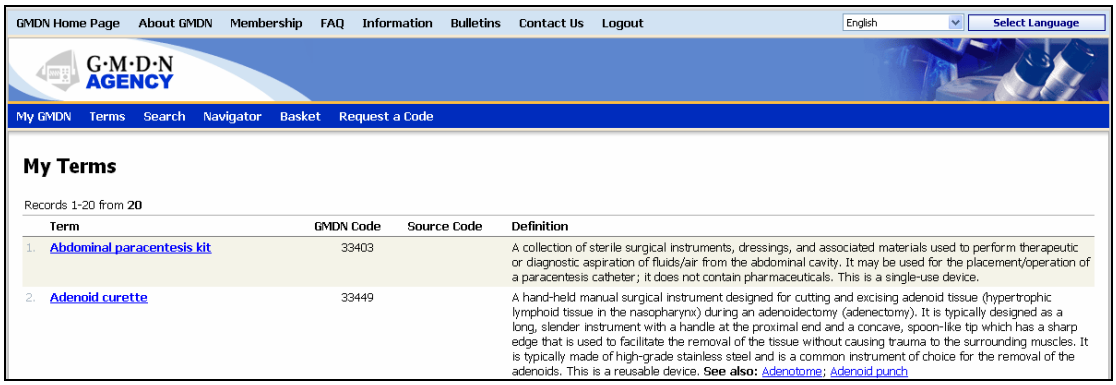

GMDN Home Page
About GMDN
Membership
FAQ
Information
Bulletins
Contact Us
Logout
English
Select Language
G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
News (click on a link below)
ISO 9999 Collaboration continues
Orthopaedic Implant Terms!
Eucomed recommends GMDN
GMDN invests in the long term
Dear Mark
Welcome to GMDN Database
You already purchased 20 term(s).
You have a balance of 103 term(s) available.
You have a balance of 2 request(s) available.
You have 3 user(s) linked to your account.
You have 0 term(s) in your basket.
GMDN Agency Service
Services provided by the GMDN Agency are:
Access to the GMDN data file and codes via this Internet site through a licence agreement and/or by direct credit card purchase.
A link from the GMDN database to the user's in-house data system through a licence agreement and a specialized software link.
Application form for new terms or modification of existing terms/definitions for the
Actions
I would like to become a member of GMDN
Continue
I would like to submit a proposal for a GMDN term
Continue
I would like to learn about the GMDN
Continue
I would like to contact the GMDN Agency
Continue

A GMDN member can enter the section on the website called *My GMDN*. This area contains information about a member and their use of the GMDN database.

7.4.2 My Terms

Select *My Terms* to find the list of the GMDN Terms previously selected by the User account holder. This list of terms is maintained by the GMDN database, which will automatically email the User if the status of any term has changed, for example if a Term Description is modified.

This feature is very useful to help maintain the GMDN codes selected by the User to the latest version, without having to regularly and repeatedly check on their status.


GMDN Home Page
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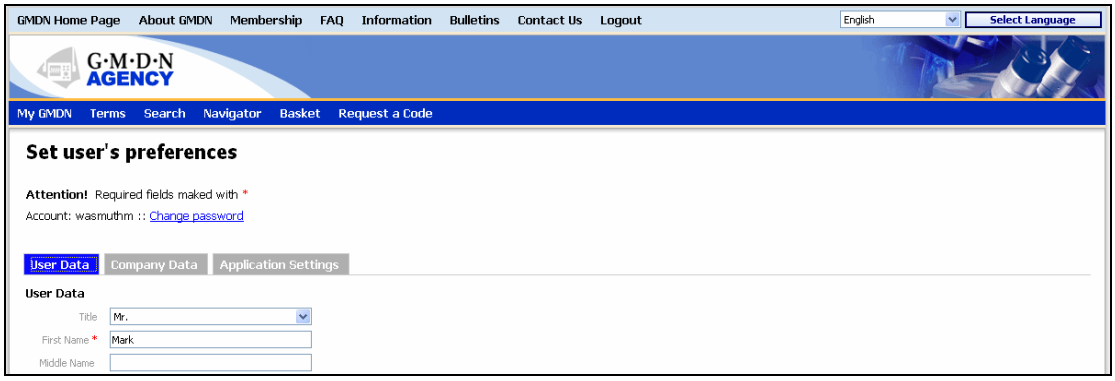
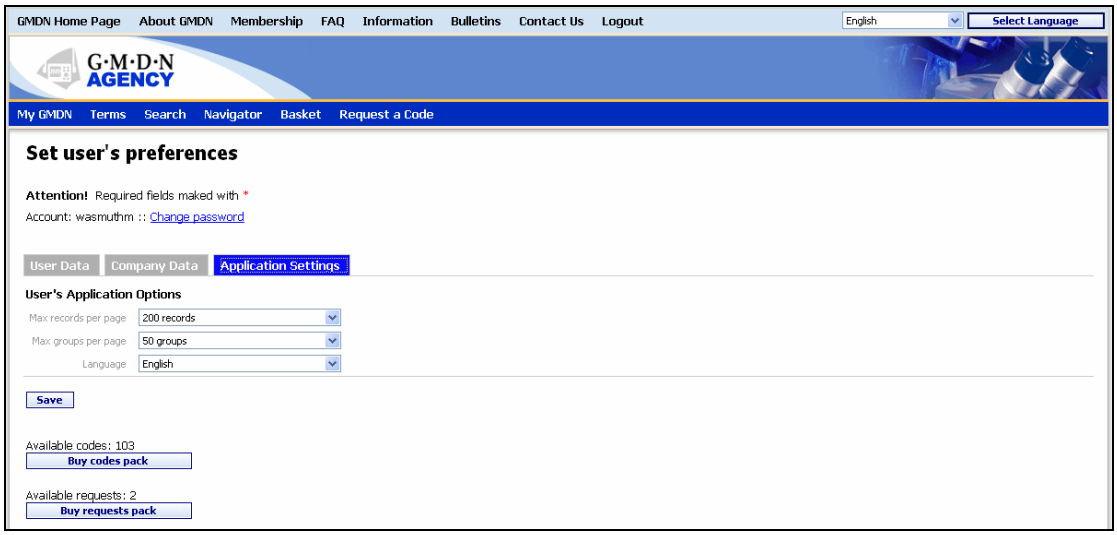
FAQ
Information
Bulletins
Contact Us
Logout
English
Select Language
G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
My Terms
Records 1-20 from 20
Term
GMDN Code
Source Code
Definition
1. Abdominal paracentesis kit
33403
A collection of sterile surgical instruments, dressings, and associated materials used to perform therapeutic or diagnostic aspiration of fluids/air from the abdominal cavity. It may be used for the placement/operation of a paracentesis catheter; it does not contain pharmaceuticals. This is a single-use device.
2. Adenoid curette
33449
A hand-held manual surgical instrument designed for cutting and excising adenoid tissue (hypertrophic lymphoid tissue in the nasopharynx) during an adenoidectomy (adenectomy). It is typically designed as a long, slender instrument with a handle at the proximal end and a concave, spoon-like tip which has a sharp edge that is used to facilitate the removal of the tissue without causing trauma to the surrounding muscles. It is typically made of high-grade stainless steel and is a common instrument of choice for the removal of the adenoids. This is a reusable device. See also: Adenotome; Adenoid punch

7.4.3 My Profile

Select *My Profile* at any time to check user details / preferences. This is a personal profile and can be used to update user information. Information such as account expiry date is also displayed.



The *Application Settings* tab can be selected to set to the number of terms that can be viewed on a computer screen. Other useful information such as balance of code / request credits is also displayed. Code Packs and New Term Request credits can be purchased by clicking on the relevant buttons.



Available codes are credits that may be used after the selection of GMDN Terms to reveal the 5 digit GMDN Codes.

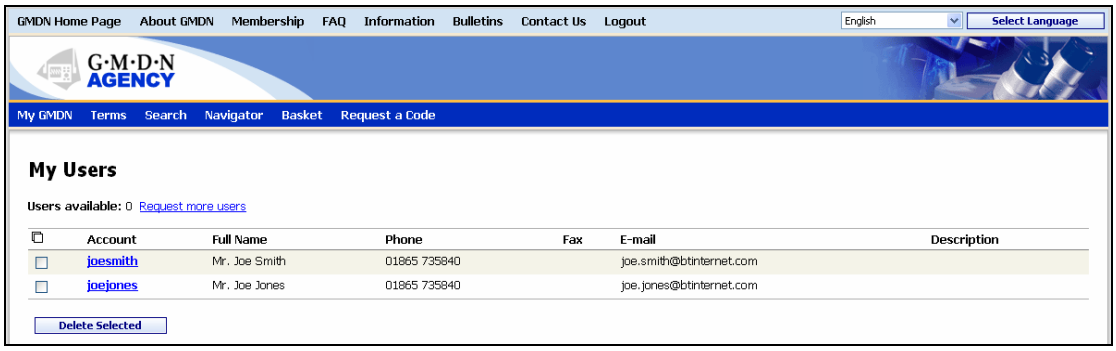
Available requests are prepaid request credits used only for New Term Requests.

Remember to click on *Save* to save the preferences.

7.4.4 My Users

If activated the User can set-up sub-users to access their account using a separate password and login. The main account holder is the Master User.

The Master User adds the new sub-user details and determines if the access rights are *Full* or *Standard*. Full access users are able to select new terms which are added to the *My Terms* list. Standard access users only have permission to look at the GMDN codes listed in *My Terms* and don't have permission to select codes.

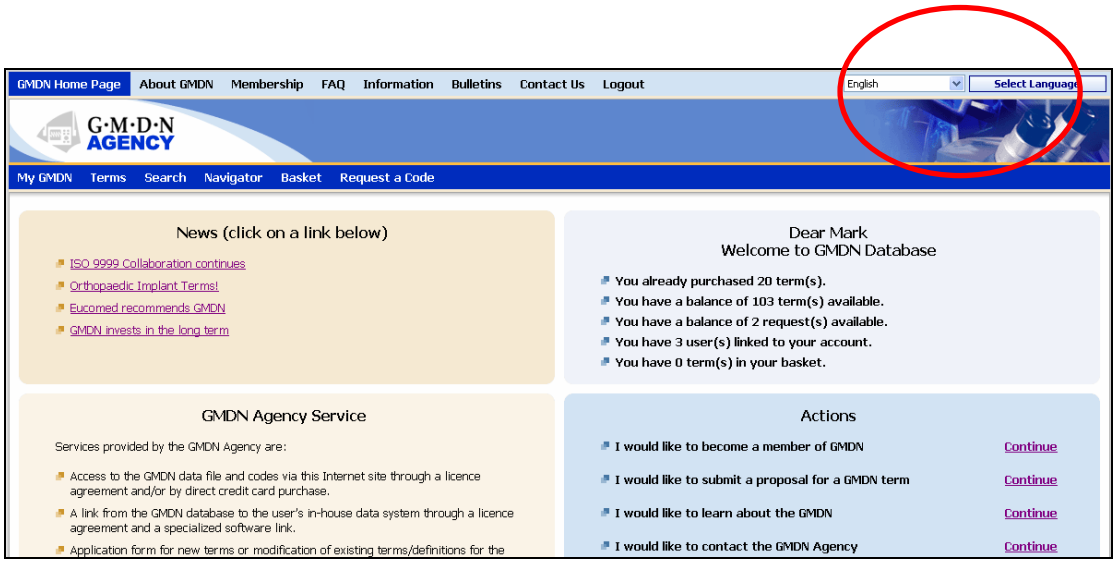


Note: This feature needs to be activated by the GMDN Agency. Please contact the GMDN Agency for more information.

7.5 GMDN Language Selection

The GMDN language option can be selected at any time from top right corner of the main screens.

Note: Translations will be made available in the GMDN web-based database once they are ready.


GMDN Home Page
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Contact Us
Logout
English
Select Language
G·M·D·N AGENCY
My GMDN
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Search
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News (click on a link below)
ISO 9999 Collaboration continues
Orthopaedic Implant Terms!
Eucomed recommends GMDN
GMDN invests in the long term
Dear Mark
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You have 0 term(s) in your basket.
GMDN Agency Service
Services provided by the GMDN Agency are:
Access to the GMDN data file and codes via this Internet site through a licence agreement and/or by direct credit card purchase.
A link from the GMDN database to the user's in-house data system through a licence agreement and a specialized software link.
Application form for new terms or modification of existing terms/definitions for the
Actions
I would like to become a member of GMDN
Continue
I would like to submit a proposal for a GMDN term
Continue
I would like to learn about the GMDN
Continue
I would like to contact the GMDN Agency
Continue

8. GMDN Search Systems

The GMDN nomenclature system is constructed so that it is fully compliant with the relative standards and conventions for a medical device nomenclature. In doing this, the GMDN provides a rich “multi-axial” approach giving many ways of searching the data for particular terms, selection of a single term, or even a word.

8.1 Searching the listings

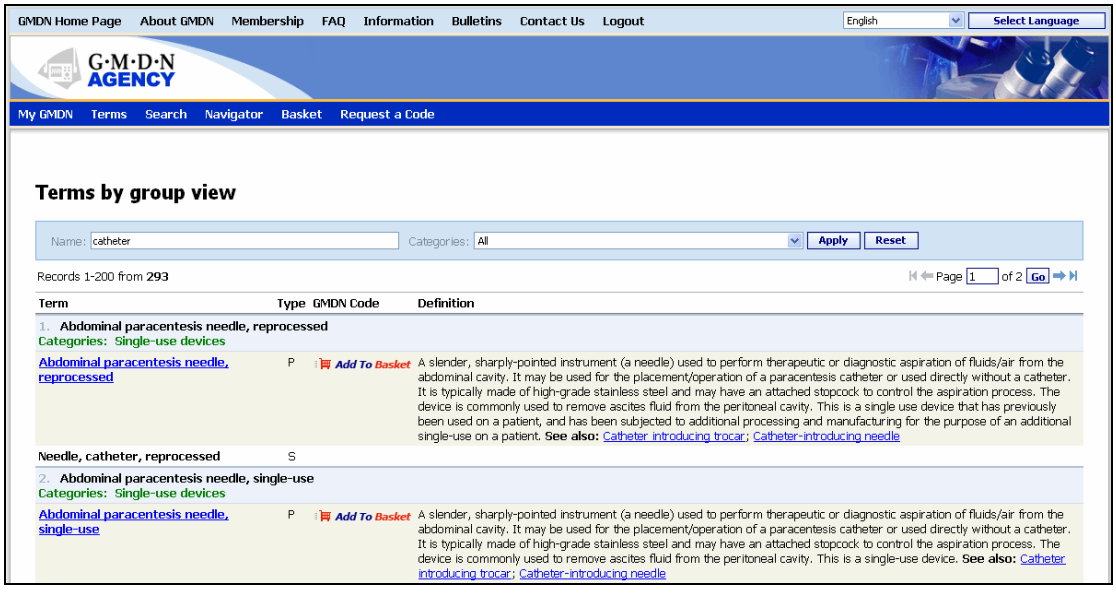
The GMDN can be viewed in three formats of listing. They are found on the second horizontal menu bar under *Terms* and are:

- Terms By Group
- Terms List
- Group List

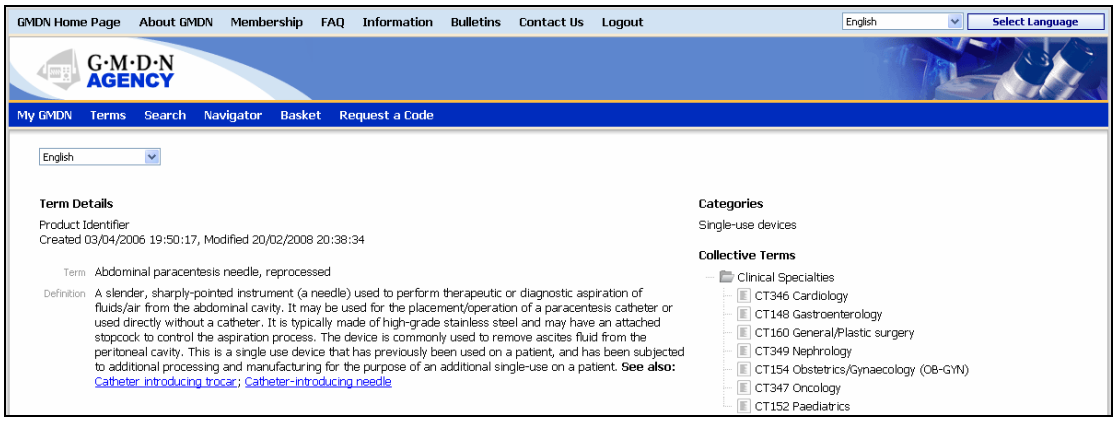
8.1.1 Terms By Group

This view gives an alphabetical listing of all the P and T terms [terms that begin with numbers (i.e. IVD terms) precede the alphabetical listing].

The listing displays the preferred term or template term as a blue hyperlink with its term type identifier and the definition (the GMDN code must be identified / purchased from current balance of *Available codes*). Below this term will be displayed linked S and MS terms, if any are linked.

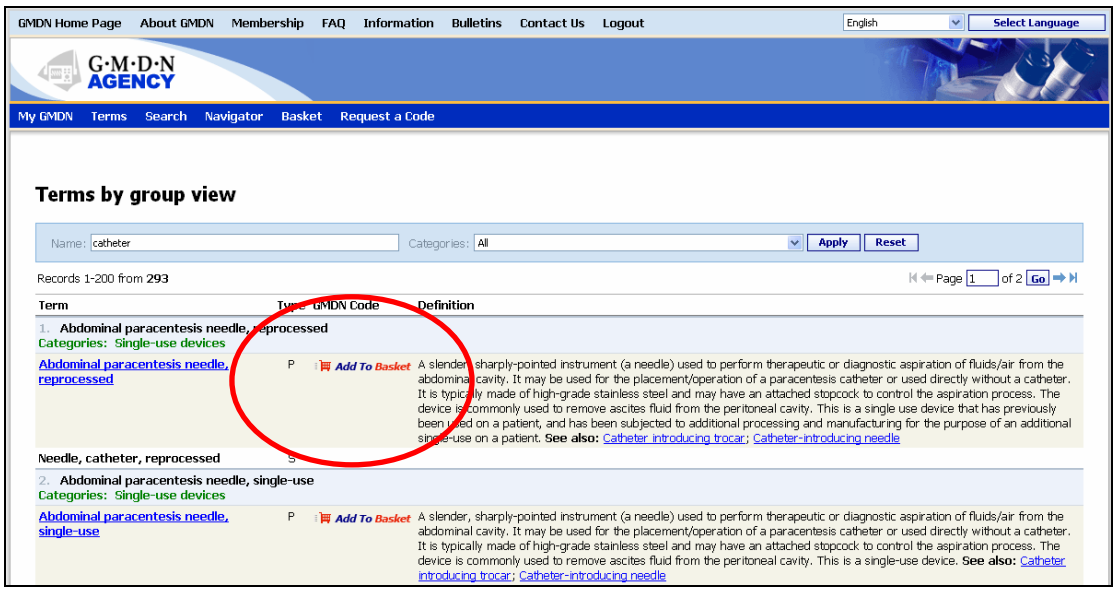

GMDN Home Page
About GMDN
Membership
FAQ
Information
Bulletins
Contact Us
Logout
English
Select Language
G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
Terms by group view
Name: catheter
Categories: All
Apply
Reset
Records 1-200 from 293
Page 1 of 2 Go
Term
Type
GMDN Code
Definition
1. Abdominal paracentesis needle, reprocessed
Categories: Single-use devices
Abdominal paracentesis needle, reprocessed
P
Add To Basket
A slender, sharply-pointed instrument (a needle) used to perform therapeutic or diagnostic aspiration of fluids/air from the abdominal cavity. It may be used for the placement/operation of a paracentesis catheter or used directly without a catheter. It is typically made of high-grade stainless steel and may have an attached stopcock to control the aspiration process. The device is commonly used to remove ascites fluid from the peritoneal cavity. This is a single use device that has previously been used on a patient, and has been subjected to additional processing and manufacturing for the purpose of an additional single-use on a patient. See also: Catheter introducing trocar; Catheter-introducing needle
Needle, catheter, reprocessed
S
2. Abdominal paracentesis needle, single-use
Categories: Single-use devices
Abdominal paracentesis needle, single-use
P
Add To Basket
A slender, sharply-pointed instrument (a needle) used to perform therapeutic or diagnostic aspiration of fluids/air from the abdominal cavity. It may be used for the placement/operation of a paracentesis catheter or used directly without a catheter. It is typically made of high-grade stainless steel and may have an attached stopcock to control the aspiration process. The device is commonly used to remove ascites fluid from the peritoneal cavity. This is a single-use device. See also: Catheter introducing trocar; Catheter-introducing needle

Clicking on any of the P term hyperlink names will open up the term to display the term details as shown below:


GMDN Home Page
About GMDN
Membership
FAQ
Information
Bulletins
Contact Us
Logout
English
Select Language
G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
English
Term Details
Product Identifier
Created 03/04/2006 19:50:17, Modified 20/02/2008 20:38:34
Term
Abdominal paracentesis needle, reprocessed
Definition
A slender, sharply-pointed instrument (a needle) used to perform therapeutic or diagnostic aspiration of fluids/air from the abdominal cavity. It may be used for the placement/operation of a paracentesis catheter or used directly without a catheter. It is typically made of high-grade stainless steel and may have an attached stopcock to control the aspiration process. The device is commonly used to remove ascites fluid from the peritoneal cavity. This is a single use device that has previously been used on a patient, and has been subjected to additional processing and manufacturing for the purpose of an additional single-use on a patient. See also:
Catheter introducing trocar; Catheter-introducing needle
Categories
Single-use devices
Collective Terms
Clinical Specialties
CT346 Cardiology
CT148 Gastroenterology
CT160 General/Plastic surgery
CT349 Nephrology
CT154 Obstetrics/Gynaecology (OB-GYN)
CT347 Oncology
CT152 Paediatrics

With membership, a pack of GMDN code credits is also provided. These credits are used to 'buy' GMDN codes. As the codes credits are used, the number of credits in the code pack account diminishes. It is an easy process to top up the code pack credits by going to *My Profile* and click on the *Buy codes pack* button.

Please note the Add To Basket icon, which is used to reveal the GMDN code.


GMDN Home Page
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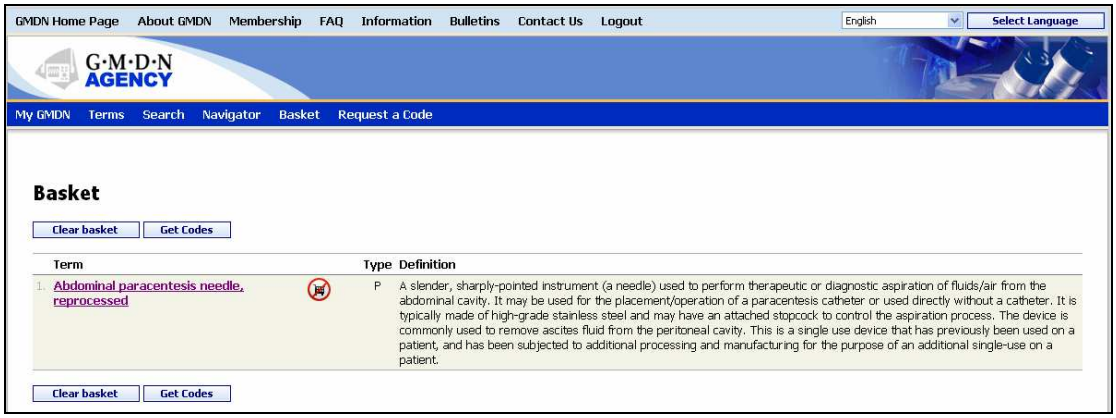
G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
Terms by group view
Name: catheter
Categories: All
Apply
Reset
Records 1-200 from 293
Page 1 of 2 Go
Term
Type
GMDN Code
Definition
1. Abdominal paracentesis needle, reprocessed
Categories: Single-use devices
Abdominal paracentesis needle, reprocessed
P
Add To Basket
A slender, sharply-pointed instrument (a needle) used to perform therapeutic or diagnostic aspiration of fluids/air from the abdominal cavity. It may be used for the placement/operation of a paracentesis catheter or used directly without a catheter. It is typically made of high-grade stainless steel and may have an attached stopcock to control the aspiration process. The device is commonly used to remove ascites fluid from the peritoneal cavity. This is a single use device that has previously been used on a patient, and has been subjected to additional processing and manufacturing for the purpose of an additional single-use on a patient. See also: Catheter introducing trocar; Catheter-introducing needle
Needle, catheter, reprocessed
S
2. Abdominal paracentesis needle, single-use
Categories: Single-use devices
Abdominal paracentesis needle, single-use
P
Add To Basket
A slender, sharply-pointed instrument (a needle) used to perform therapeutic or diagnostic aspiration of fluids/air from the abdominal cavity. It may be used for the placement/operation of a paracentesis catheter or used directly without a catheter. It is typically made of high-grade stainless steel and may have an attached stopcock to control the aspiration process. The device is commonly used to remove ascites fluid from the peritoneal cavity. This is a single-use device. See also: Catheter introducing trocar; Catheter-introducing needle

After selected the icon changes to the symbol and added to the list in the *Basket*. When the Basket is opened the list of selected terms is displayed and the User can then click the *Get Codes* button to reveal the GMDN Code.


GMDN Home Page
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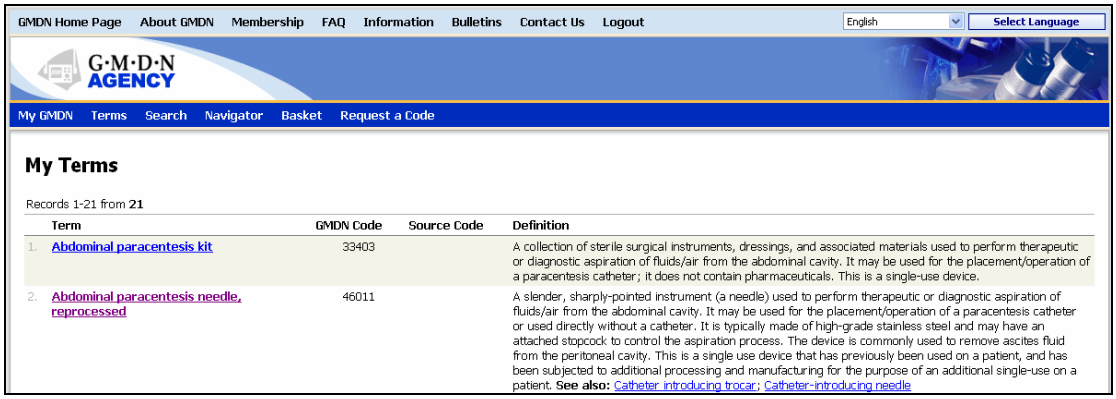
G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
Basket
Clear basket
Get Codes
Term
Type
Definition
1. Abdominal paracentesis needle, reprocessed
P
A slender, sharply-pointed instrument (a needle) used to perform therapeutic or diagnostic aspiration of fluids/air from the abdominal cavity. It may be used for the placement/operation of a paracentesis catheter or used directly without a catheter. It is typically made of high-grade stainless steel and may have an attached stopcock to control the aspiration process. The device is commonly used to remove ascites fluid from the peritoneal cavity. This is a single use device that has previously been used on a patient, and has been subjected to additional processing and manufacturing for the purpose of an additional single-use on a patient.
Clear basket
Get Codes

As GMDN codes are purchased, these are displayed to the GMDN member only and stored in *My Terms*. This is a personal cache of purchased GMDN codes and is password protected within the account.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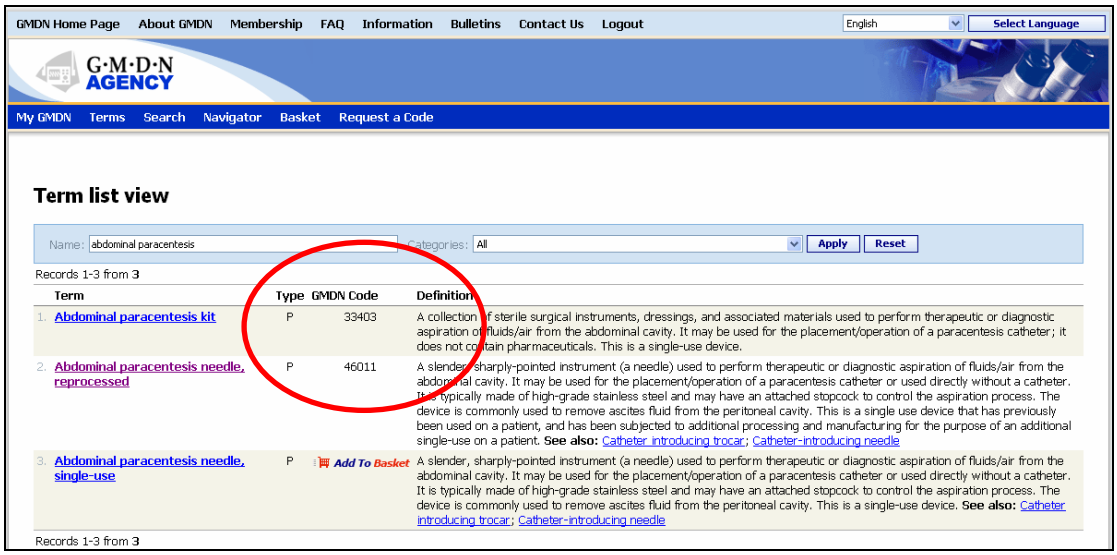
Select Language
G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
My Terms
Records 1-21 from 21
Term
GMDN Code
Source Code
Definition
1. Abdominal paracentesis kit
33403
A collection of sterile surgical instruments, dressings, and associated materials used to perform therapeutic or diagnostic aspiration of fluids/air from the abdominal cavity. It may be used for the placement/operation of a paracentesis catheter; it does not contain pharmaceuticals. This is a single-use device.
2. Abdominal paracentesis needle, reprocessed
46011
A slender, sharply-pointed instrument (a needle) used to perform therapeutic or diagnostic aspiration of fluids/air from the abdominal cavity. It may be used for the placement/operation of a paracentesis catheter or used directly without a catheter. It is typically made of high-grade stainless steel and may have an attached stopcock to control the aspiration process. The device is commonly used to remove ascites fluid from the peritoneal cavity. This is a single use device that has previously been used on a patient, and has been subjected to additional processing and manufacturing for the purpose of an additional single-use on a patient. See also: Catheter introducing trocar; Catheter-introducing needle

8.1.2 Terms List

This gives an alphabetical listing of all P terms with their definitions directly viewable.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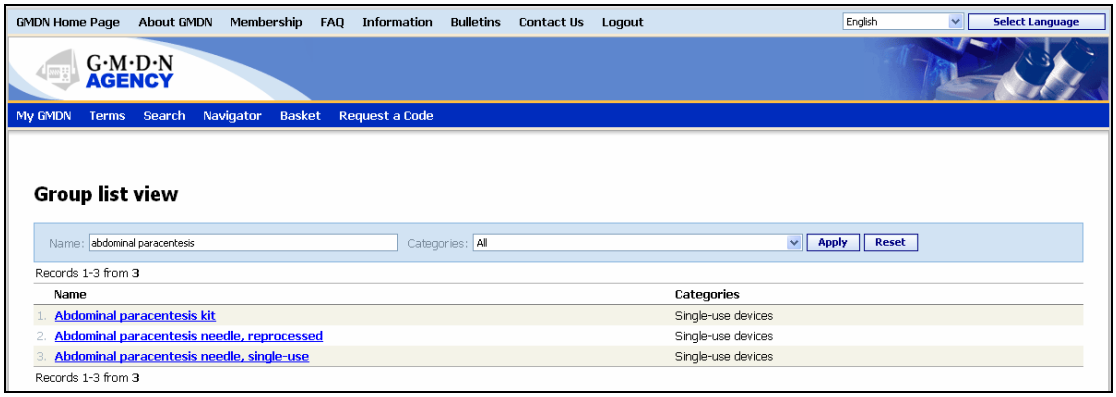
English
Select Language
G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
Term list view
Name: abdominal paracentesis
Categories: All
Apply
Reset
Records 1-3 from 3
Term
Type
GMDN Code
Definition
1. Abdominal paracentesis kit
P
33403
A collection of sterile surgical instruments, dressings, and associated materials used to perform therapeutic or diagnostic aspiration of fluids/air from the abdominal cavity. It may be used for the placement/operation of a paracentesis catheter; it does not contain pharmaceuticals. This is a single-use device.
2. Abdominal paracentesis needle, reprocessed
P
46011
A slender, sharply-pointed instrument (a needle) used to perform therapeutic or diagnostic aspiration of fluids/air from the abdominal cavity. It may be used for the placement/operation of a paracentesis catheter or used directly without a catheter. It is typically made of high-grade stainless steel and may have an attached stopcock to control the aspiration process. The device is commonly used to remove ascites fluid from the peritoneal cavity. This is a single use device that has previously been used on a patient, and has been subjected to additional processing and manufacturing for the purpose of an additional single-use on a patient. See also: Catheter introducing trocar; Catheter-introducing needle
3. Abdominal paracentesis needle, single-use
P
Add To Basket
A slender, sharply-pointed instrument (a needle) used to perform therapeutic or diagnostic aspiration of fluids/air from the abdominal cavity. It may be used for the placement/operation of a paracentesis catheter or used directly without a catheter. It is typically made of high-grade stainless steel and may have an attached stopcock to control the aspiration process. The device is commonly used to remove ascites fluid from the peritoneal cavity. This is a single-use device. See also: Catheter introducing trocar; Catheter-introducing needle
Records 1-3 from 3

Please note, that as GMDN terms are purchased, the codes are displayed in the views.

8.1.3 Group List

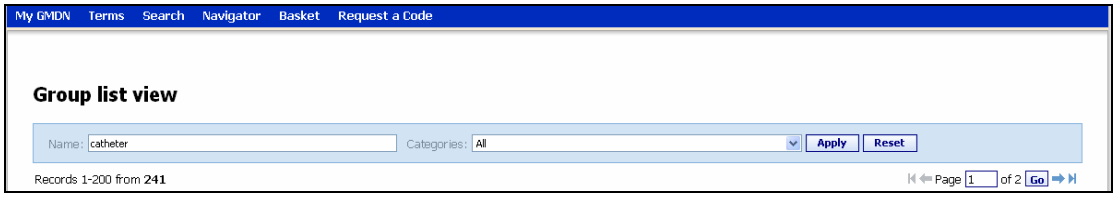
This view gives an alphabetical listing of all the P and T terms [terms that begin with numbers (i.e. IVD terms) precede the alphabetical listing]. This presentation provides more terms per screen to view at one time. By clicking on any one of the term hyperlinks, *Terms By Group* view is opened.



8.2 Term search using Filters

Since the terms are listed alphabetically one can scroll up and down the list until the term or similar groups of terms are found. However, with the total number of P and T terms close to 20,000 and the number of terms available in one view being limited, this process would be very tiresome.

Using the *Filters* a GMDN member can narrow this search by putting search criteria into one or both of the *Filters* fields. For example, by searching on Catheter in the *Name* box and by selecting an appropriate category from the drop-down list in the *Categories* box, all the P terms that include these filter criteria are displayed:



Furthermore, if selecting the GMDN Category of interest, e.g., Dental devices, Reusable devices, add this into the *Categories* filter and this again would narrow the search.

To clear this search, click on the *Reset* and then the *Apply* button, or type in new search criteria and click on *Apply*.

8.3 Synonym search

The GMDN is supported by many synonym terms that may direct the user directly to the term being sought. To find P terms using the synonyms, use the search engine.

8.4 Category search

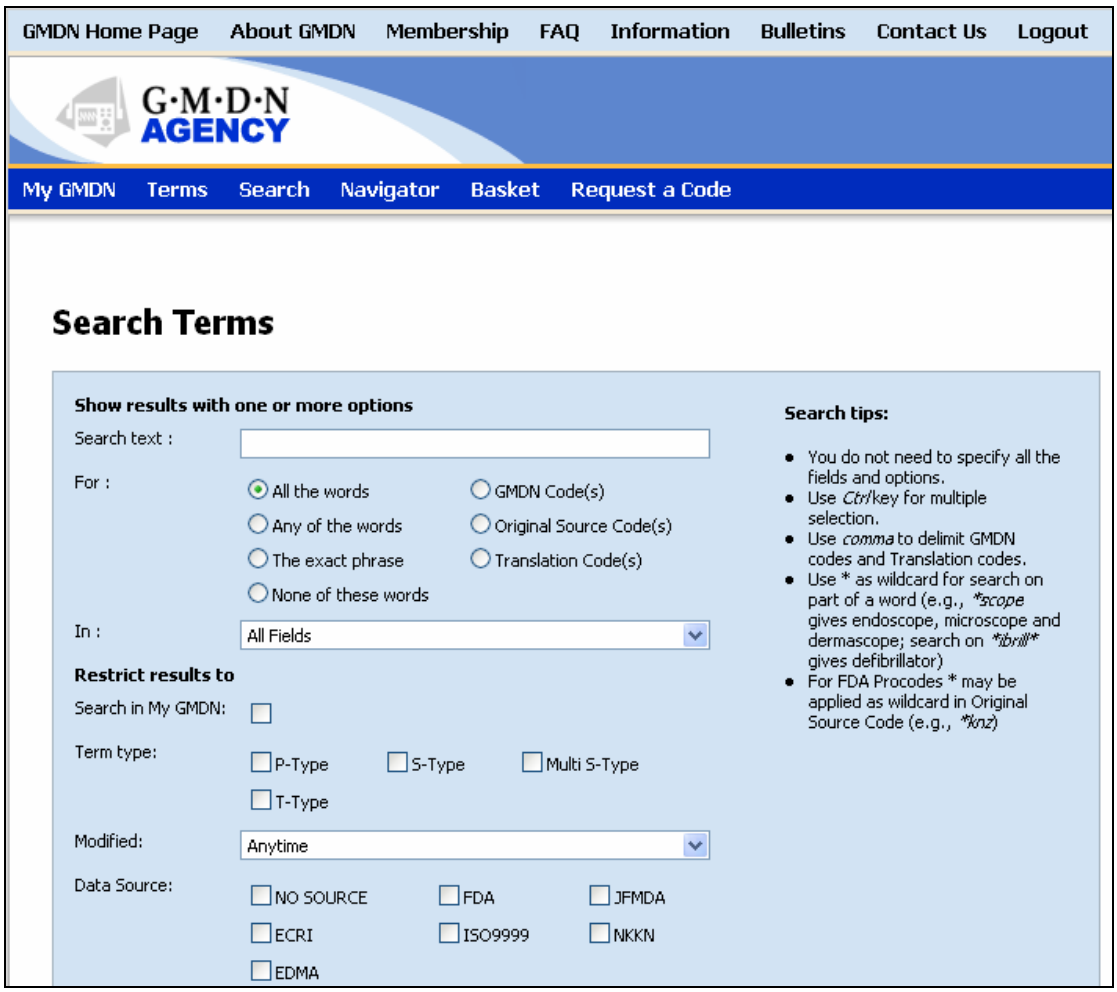
A search by Category can be performed to narrow the data to a specific medical specialty, technology, or intended use (e.g., dental devices, in vitro diagnostic devices, or electromechanical medical devices).

A product made, for example, for dental use will be found in Category Dental devices. Selecting Category Dental devices will produce a listing of terms related to this speciality. Remember to click the *Reset* and then *Apply* buttons when finished.

The Categories with their definitions can be viewed at any time by clicking on the quick link information found on the top horizontal menu bar of the database and drop-down menu.

8.5 GMDN Search engine

The GMDN search engine has been designed to provide the user with a rich search system that can refine the search criteria, limiting the search and search results to the specific terms of interest of the user. By clicking on *Search* on the second horizontal menu bar the search engine will appear. It looks like this:



The search criteria, whether this be a word, a word string, a partial word, a GMDN code, or an original source code, has to be entered into the *Search text:* field and the correct selection at *For:* must be chosen. Searching by a chosen word can have two targets, it can target the term or by hitting the word in the definition.

Search tips are:

- Specifying all the fields and options is not needed.
- Use *Ctrl* key for multiple selection.
- Use *comma* to delimit GMDN codes.
- Use * as wildcard for search on part of a word (e.g., **scope* gives endoscope, microscope and dermascope; search on **ibrill** gives defibrillator)
- For FDA Procodes * may be applied as wildcard in Original Source Code (e.g., **knz*)

Remember, for each search criteria added to a search will narrow the number of terms that are found. By adding too many search criteria, the search engine may not find any hits at all.

Click on the *Search* button to start the search, and click on *Clear form* to clear the search criteria.

8.6 Search using codes

It is possible to search on terms by using a code.

GMDN codes: if a GMDN code is known, then enter this in Search text: field of the search engine, click on the radio button *GMDN Code(s)* and the database will display the related term or terms to which it is linked. Try for example 45717.

ECRI (UMDNS) codes: if an ECRI (UMDNS) code is known, then enter this in Search text: field of the search engine, click on the radio button *Original Source code(s)* and the database will display the related term or terms to which it is linked. Try for example 16-168 but always remove the hyphen and enter like so 16168.

EDMA codes: if an EDMA code is known, then enter this in Search text: field of the search engine, click on the radio button *Original Source code(s)* and the database will display the related term or terms to which it is linked. Try for example 13 02 70 02 00 (always enter the EDMA code in the original format with spaces).

FDA Procodes: if an FDA Procode is known, then enter this in Search text: field of the search engine, click on the radio button *Original Source code(s)*

and the database will display the related term or terms to which it is linked. Try for example CBK.

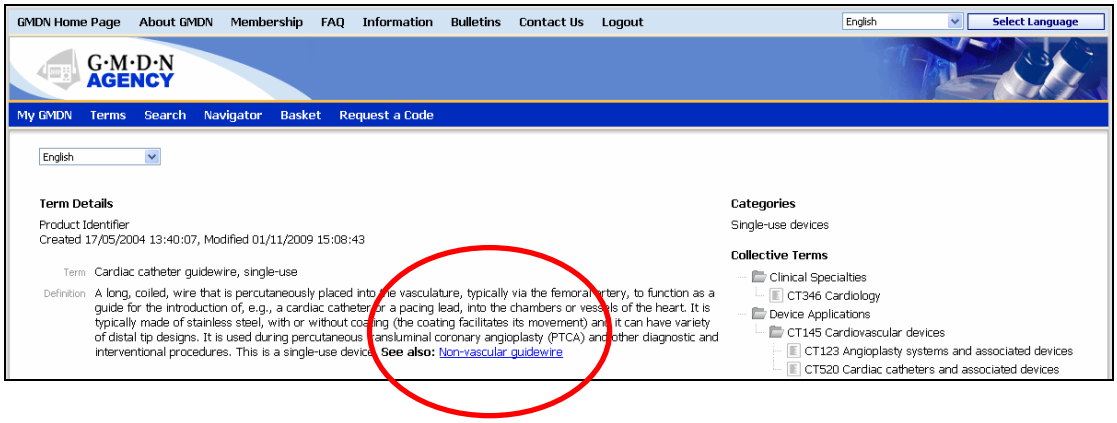
JFMDA codes: if a JFMDA code is known, then enter this in Search text: field of the search engine, click on the radio button *Original Source code(s)* and the database will display the related term or terms to which it is linked. (always enter the JFMDA code in the original format with spaces).

NKKN codes: if an NKKN code is known, then enter this in Search text: field of the search engine, click on the radio button *Original Source code(s)* and the database will display the related term or terms to which it is linked. Try for example 12002.

8.7 Cross-referenced Preferred terms

To indicate related or alternative preferred terms that may be of interest, the GMDN database includes a system of cross-referenced preferred terms.

These are the dark blue hyperlinked term names preceded by *See also:* at the end of each definition.


GMDN Home Page
About GMDN
Membership
FAQ
Information
Bulletins
Contact Us
Logout
English
Select Language
G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
English
Term Details
Product Identifier
Created 17/05/2004 13:40:07, Modified 01/11/2009 15:08:43
Term
Cardiac catheter guidewire, single-use
Definition
A long, coiled, wire that is percutaneously placed into the vasculature, typically via the femoral artery, to function as a guide for the introduction of, e.g., a cardiac catheter or a pacing lead, into the chambers or vessels of the heart. It is typically made of stainless steel, with or without coating (the coating facilitates its movement) and it can have variety of distal tip designs. It is used during percutaneous transluminal coronary angioplasty (PTCA) and other diagnostic and interventional procedures. This is a single-use device. See also: Non-vascular guidewire
Categories
Single-use devices
Collective Terms
Clinical Specialties
CT346 Cardiology
Device Applications
CT145 Cardiovascular devices
CT123 Angioplasty systems and associated devices
CT520 Cardiac catheters and associated devices

By clicking on any one of the referenced hyperlinked *See also:* P terms the system will display the term details of that hyperlinked term.

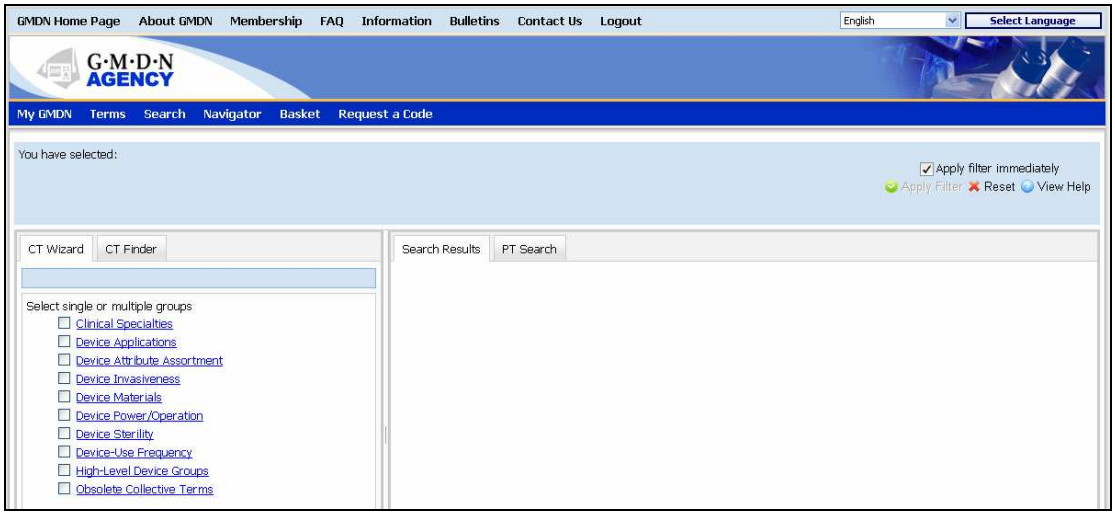
Use the Back arrow on the Browser to return to the previous term view.

9. GMDN Navigator

The GMDN Navigator is an advanced search tool for in-depth analysis of the GMDN P term data through selection of Collective Terms which can be further refined using this in combination with the GMDN search engine.

The system includes hierarchical constructs that are poly-hierarchical in nature, meaning that a particular preferred term or collective term is capable of existing in more than one hierarchy, which maximizes flexibility and utility to provide a unique system for searching, locating, and viewing GMDN P terms.

The Navigator view looks like this:



The Navigator is designed with a split (divided) screen which users can adjust by placing the cursor on the vertical division, left mouse click, hold and drag the vertical division left or right, this enable a view for more of the data of interest.

The Navigator enables users to find Collective Terms (CTs) [high-level terms displayed on the left side of the screen] and their corresponding Preferred Terms (PTs) [product-identification terms, displayed on the right side of the screen], and to move through CT hierarchical constructs in the nomenclature.

The high-level terms on the left (these are not the CTs but headers under which the CTs are grouped) are:

- Clinical Specialities
- Device Applications
- Device Attributes
- Device Invasiveness
- Device Materials
- Device Power/Operation
- Device Sterility
- Device-Use Frequency

- High-Level Device Groups
- Obsolete Collective Terms

Note: Obsolete Collective Terms are CTs that have been retired and which have no P term links and are of no interest to the User.

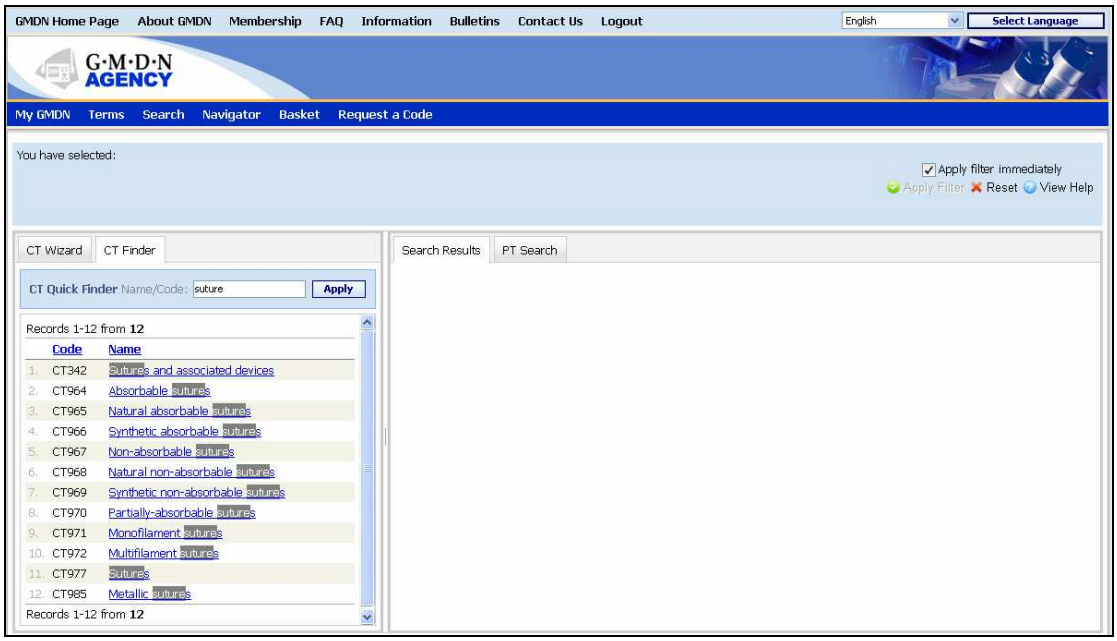
9.1 Getting started

The Navigator is not as challenging as it may first look and a recommended way to get started and familiarized is as follows:

9.1.1 CT Finder

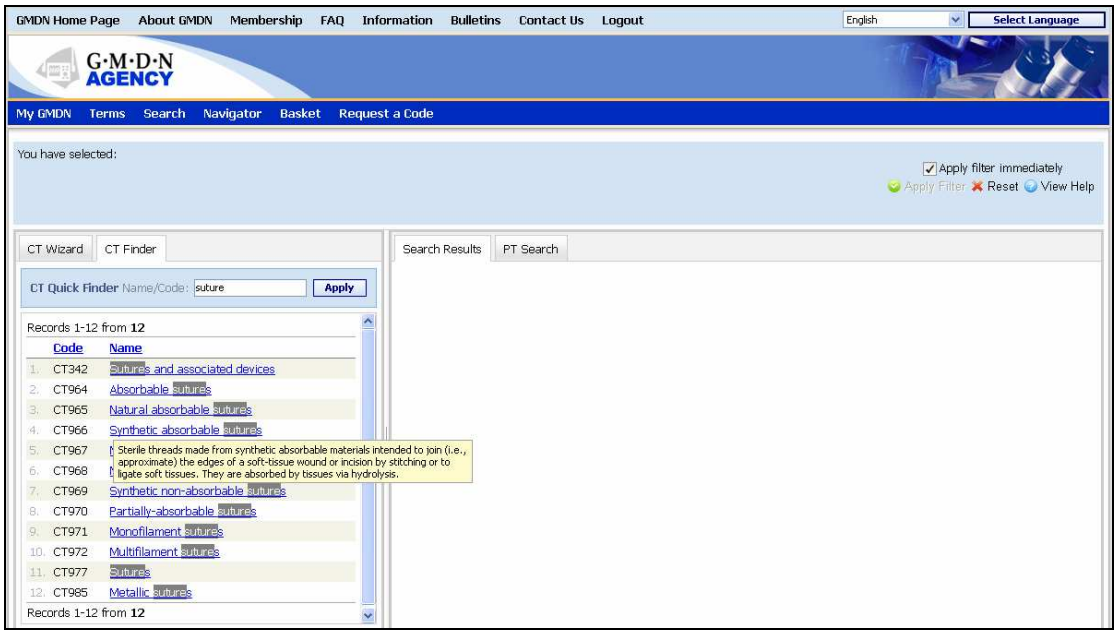
To find a CT, select the *CT Finder* tab and enter a device name or attribute or CT code, into the *Name/Code* field and click *Apply*.

Try for example the word suture as shown below:



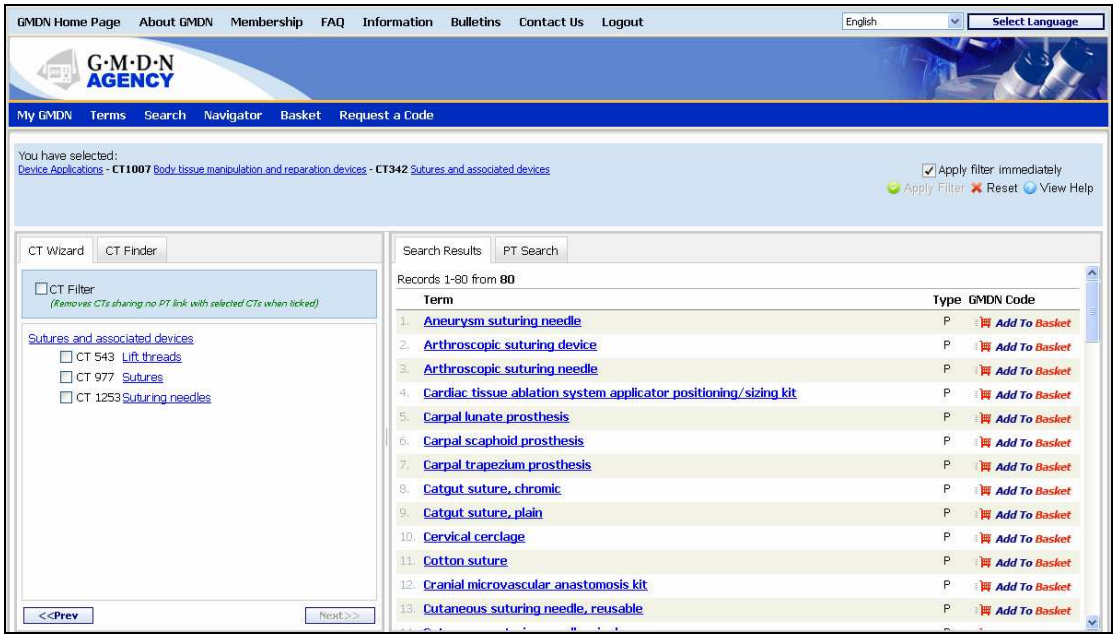
The CT search result shows all CTs where the letter string suture is found in the CT term name and/or the definition.

By placing the cursor over a CT name, a dialogue box will display its definition helping the user understand the scope of this CT as shown below:



9.1.2 CT Wizard

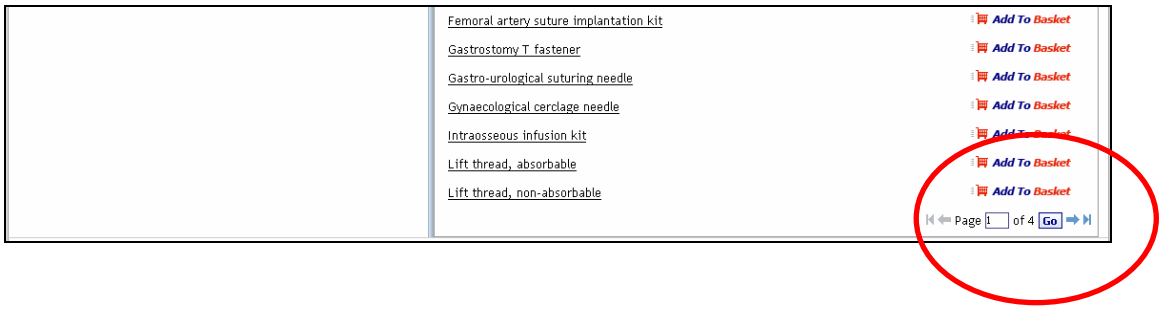
By clicking on the Collective Term name (the hyperlink) of choice, for example CT342 Sutures and associated devices, the system will automatically switch to the *CT Wizard*.



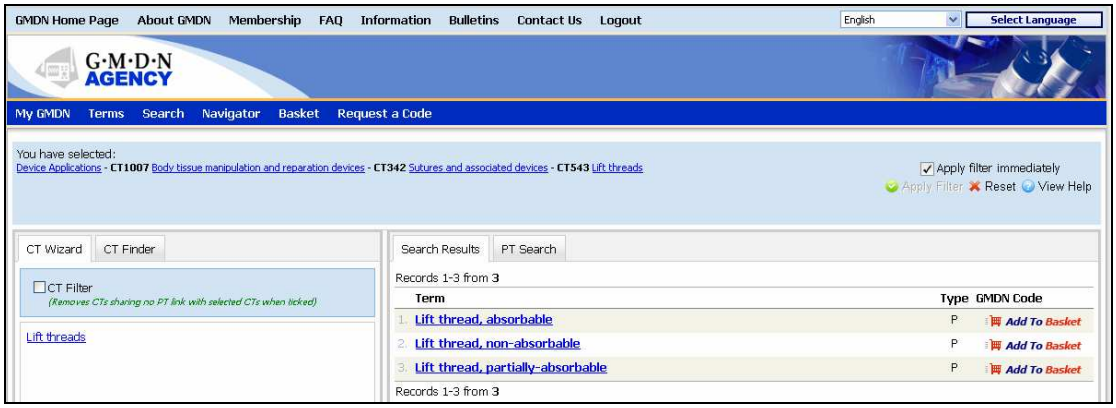
The right side of the Navigator now displays the number of P terms that are currently related (linked) to CT342 Sutures and associated devices.

Note: At the bottom of the *Search Results* pane is displayed the page counter, when there are more results than can be viewed on one page.

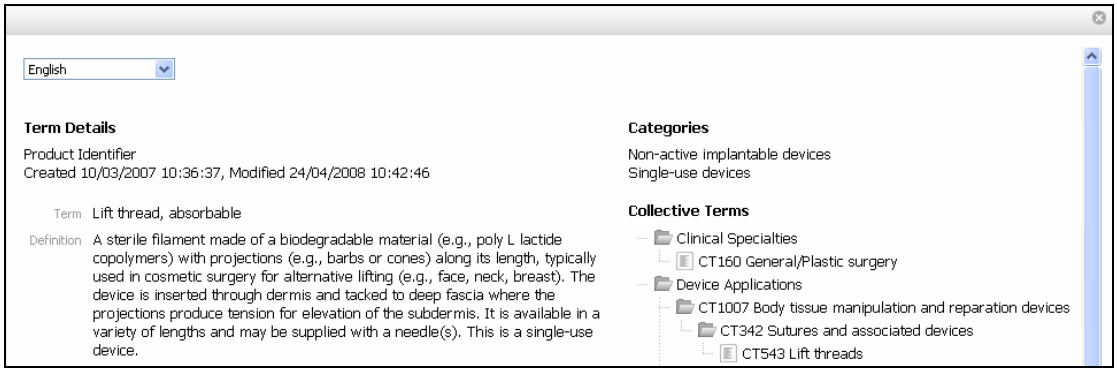
Use this function to move back and forth through the list of displayed preferred terms. See below:



Furthermore, the search on CT342 Sutures and associated devices displays all the CTs that are subordinated under CT342 Sutures and associated devices. By selecting on any one of these the P term results, for example CT543 Lift threads, are further refined as shown below:

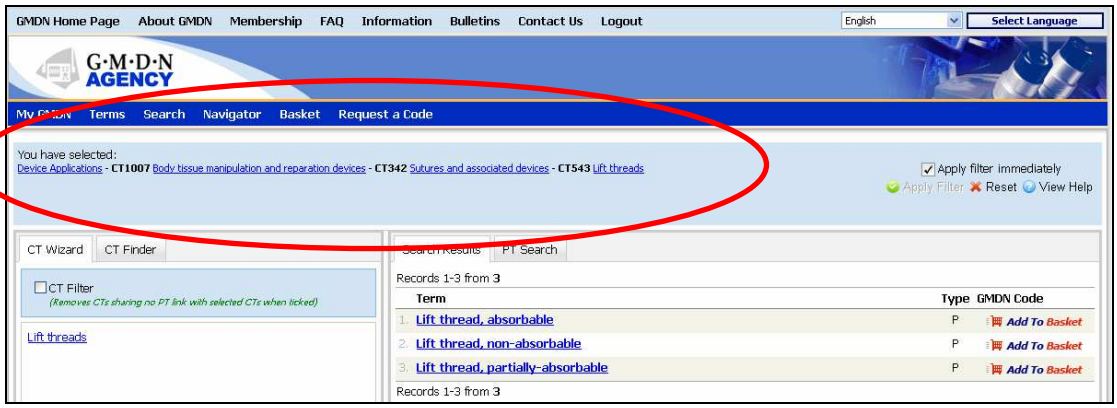


In the right hand pane are all of the preferred terms that are linked to CT543 Lift threads. Here can be seen the full term definition and other term details by putting the cursor over the P term name and left mouse click. A second term details window will open as shown below:

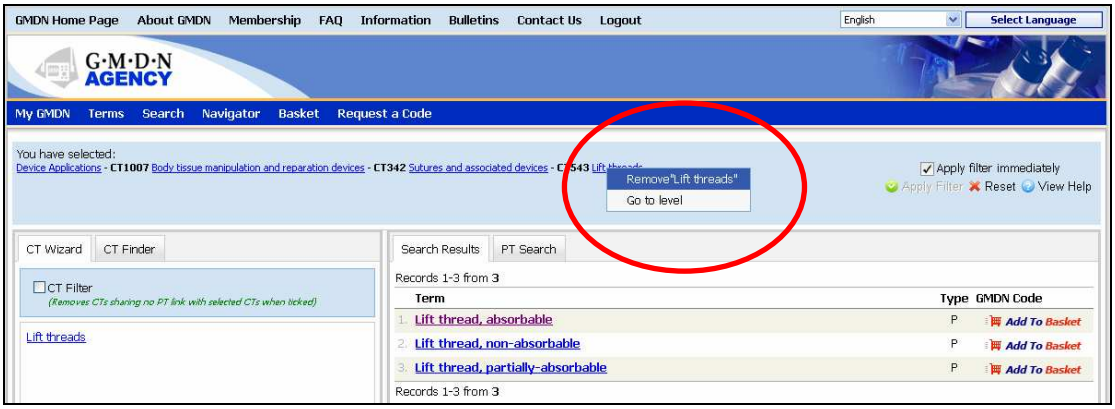

English
Term Details
Product Identifier
Created 10/03/2007 10:36:37, Modified 24/04/2008 10:42:46
Term Lift thread, absorbable
Definition A sterile filament made of a biodegradable material (e.g., poly L lactide copolymers) with projections (e.g., barbs or cones) along its length, typically used in cosmetic surgery for alternative lifting (e.g., face, neck, breast). The device is inserted through dermis and tacked to deep fascia where the projections produce tension for elevation of the subdermis. It is available in a variety of lengths and may be supplied with a needle(s). This is a single-use device.
Categories
Non-active implantable devices
Single-use devices
Collective Terms
Clinical Specialties
CT160 General/Plastic surgery
Device Applications
CT1007 Body tissue manipulation and reparation devices
CT342 Sutures and associated devices
CT543 Lift threads

Click on the red **X** in the top right corner to close this window.

The CTs selected as part of the search are displayed in the blue bar, for example:



To remove any selected CT from the search criteria, put the cursor over the selected CT displayed in the blue bar and right mouse click. A remove feature will open as shown below:

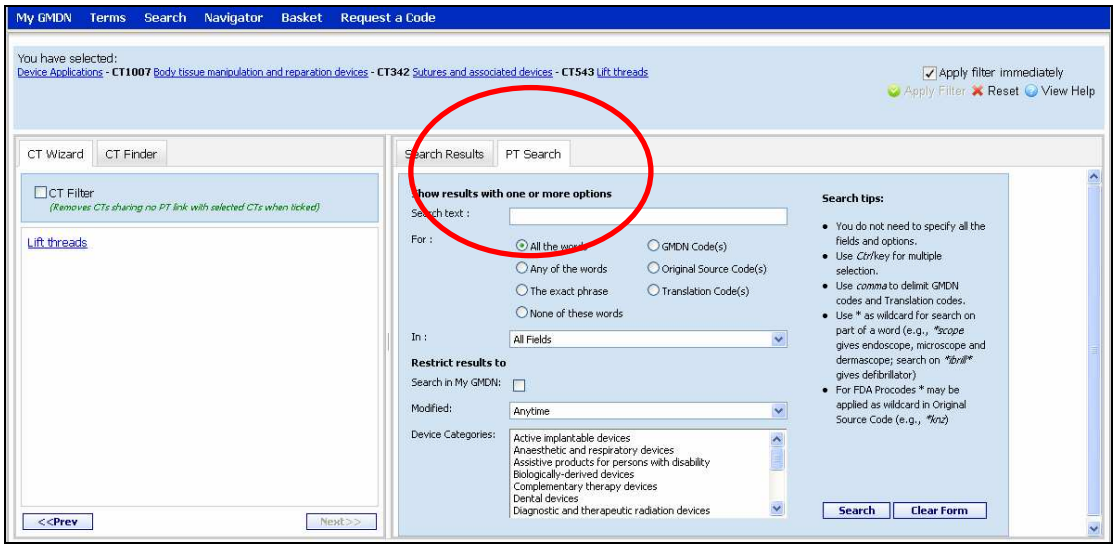


To display P terms that have multiple CTs of interest in common (e.g., Sterile and Dental devices), select one or more search titles followed by multiple CTs (use check boxes).

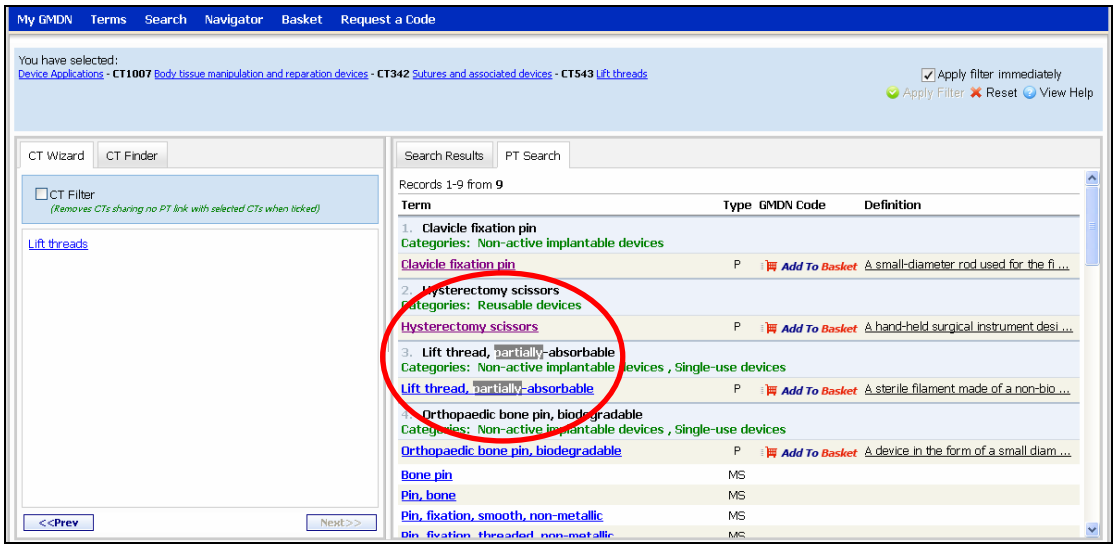
Check the CT filter box to exclusively display CTs that have P terms in common with CTs you select to facilitate a search.

9.2 Refining the P term search results

P terms can be refined after selecting a CT(s), or directly searched for, by selecting the *PT Search* tab.

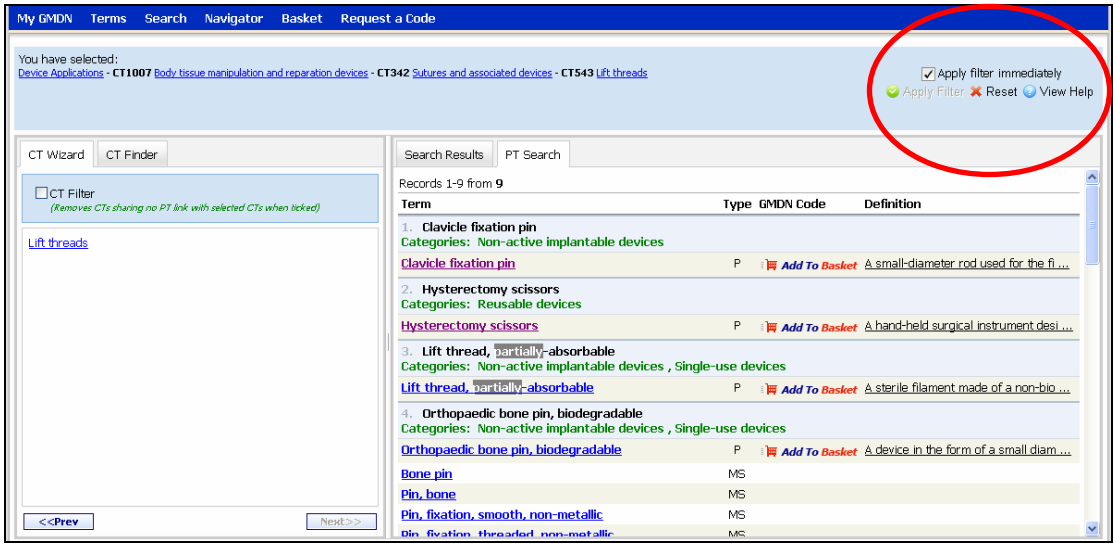

My GMDN
Terms
Search
Navigator
Basket
Request a Code
You have selected:
Device Applications - CT1007 Body tissue manipulation and reparation devices - CT342 Sutures and associated devices - CT543 Lift threads
Apply filter immediately
Apply Filter
Reset
View Help
CT Wizard
CT Finder
CT Filter
(Removes CTs sharing no PT link with selected CTs when ticked)
Lift threads
<<Prev
Next>>
Search Results
PT Search
Show results with one or more options
Search text :
For :
All the words
Any of the words
The exact phrase
None of these words
GMDN Code(s)
Original Source Code(s)
Translation Code(s)
In :
All Fields
Restrict results to
Search in My GMDN:
Modified:
Anytime
Device Categories:
Active implantable devices
Anaesthetic and respiratory devices
Assistive products for persons with disability
Biologically-derived devices
Complementary therapy devices
Dental devices
Diagnostic and therapeutic radiation devices
Search tips:
You do not need to specify all the fields and options.
Use Ctrl key for multiple selection.
Use comma to delimit GMDN codes and Translation codes.
Use * as wildcard for search on part of a word (e.g., *scope gives endoscope, microscope and dermascope; search on *ibril* gives defibrillator)
For FDA Procodes * may be applied as wildcard in Original Source Code (e.g., *knz)
Search
Clear Form

In this example the search text partially has been entered into the *Search text:* field of the search engine and searched on. This has narrowed the search results using the CT543 Lift threads filter to the most relevant P term only Lift thread, partially-absorbable as shown below:



This feature is particularly useful to focus a search when many P terms are linked to a selected CT(s), or to initiate a customized search when searching for P terms that may be difficult to find using the CTs.

Remember to clear all selections when starting a new search. Click on X *Reset* in the blue bar.



Important Note: the links between collective terms and preferred terms cannot be 100% due to the continual development and expansion of these terms in the GMDN database, therefore the use of the CTs in searching for preferred terms should not be considered as exhaustive.

10. Product Identification Using a GMDN Code

10.1 GMDN Term Selection

Identifying a medical device or product with the correct GMDN is very important and a matter to be taken seriously. The days of cavalier code assignment are over.

It is the definition that describes the scope of the term and code. If the definition does not accurately describe a product then its associated code should not be applied to the product. If no GMDN term with its definition is appropriate then a GMDN Request should be submitted to the GMDN Agency for a new term or a modification to an existing P term.

Note: Specific examples are often used in GMDN definitions to facilitate conceptualization of a medical device group (e.g., physical description, clinical application, material). The examples are not meant to be exhaustive, or to exclude products that fit the general description of the definition but which are not specifically described by the examples.

10.1.1 Rules for Specific Product/Term Selection

Within the GMDN system, products are to be assigned a GMDN code based on the following list of rules:

1. All devices that are placed onto the market shall be identified using an applicable GMDN code, which through its term and definition shall clearly define the intended use of the device, the clinical field and/or the anatomical target site of application, the technology employed, and the specific criteria attributed by the manufacturer of the device, e.g., sterile, non-sterile, reusable, single-use, drug-eluting, indwelling, etc.
2. Each device that is placed onto the market as an individual product shall have a GMDN code.
3. Each device that is placed onto the market as a system (meaning an assembly of component devices) shall have a GMDN code.
4. Each component device of a system that can be placed onto the market as a single product, e.g., sold as a replacement for a defect component device of the system so that the system can continue to function for the user, shall have a GMDN code. Note: If the component devices are always marketed as a package and are never as individual device, then rule 2 is applied.
5. Each device that is placed onto the market as a kit or a set (meaning a collection of devices) shall have a GMDN code.
6. Each device that is included in a kit or a set, but that can also be placed onto the market as an individual product (meaning it is also available as an individual device as well as being available in the kit or set) shall have a GMDN code. Note: If the devices in a kit or a set are always sold packaged together and are never placed onto the market as individual device, then rule 5 is applied.

7. Each device that is an accessory to a device and that is placed onto the market shall have a GMDN code. An accessory is defined as a significant component of a device critical to its function (e.g., the rotor head of a centrifuge).
8. No device that is placed onto the market as an individual product, system, set or kit, or an accessory, can be represented by using two GMDN codes to achieve an appropriate description, e.g., a tubing set that has a dual function for irrigation and suction cannot use the two GMDN terms for these two individual intended purposes, the device must have one applicable GMDN term and code describing this combined function.

The method for device/product identification used should be:

1. **Search** the GMDN database for the most specific applicable preferred term.
2. **Check** that the definition is appropriate. If not, submit a GMDN Request for a suggestion for an improvement, correction, or new term.
3. **Check** that the device category or at least one of the categories already indicated and linked to the selected preferred term is applicable for a device/product. If not, submit a GMDN Request for an additional category.
4. **Register** the product using the GMDN 5 digit code, and the related data (term and definition) if asked for, to the regulatory authority, hospital, or body requesting this information.

A non-exhaustive list of term specificity is provided in a table at the end of this User Guide to provide the user with an indication of how specific GMDN preferred terms are, and by the criteria required by regulatory bodies to generically group and register devices.

10.2 Category linkage

A preferred term is linked to at least one category, although in many cases it will be appropriately linked to more than one category.

EXAMPLE:
Preferred term: Infusion pump, general-purpose
Code: 13215
Categories: 2, 4, 11

This device could theoretically function in an anaesthesiology setting, a general-purpose hospital/institution setting, or as an aid for a person with a disability. The product’s intended purpose does, of course, totally depend upon the manufacturer’s device type design.

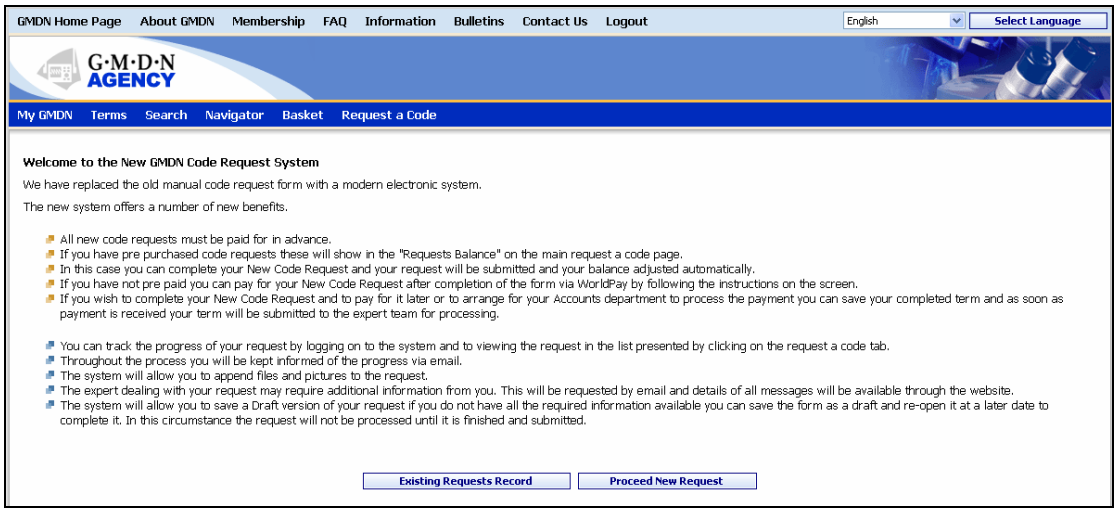
10.3 Products in the clinical testing phase

For medical devices that are in the clinical testing phase there may arise problematic circumstances for the manufacturer, such as the regulatory authority may demand a GMDN code for the product as part of the final

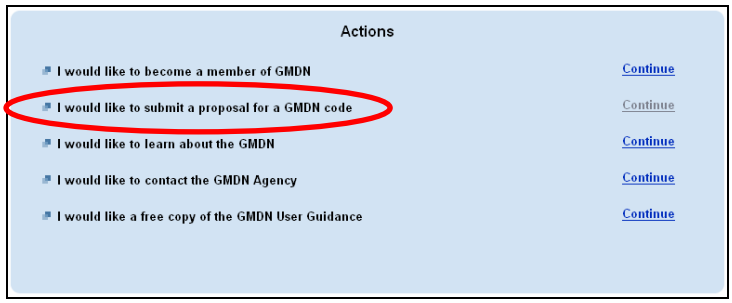
documentation and approval process. The GMDN Agency, on the other hand, does not want to have its database full of terms and codes for devices that have not yet been put onto the market, or that may never be marketed. In order to alleviate this situation, the GMDN Agency has made the provision that such requests from manufacturers can be allowed on an ad hoc basis as deemed best by the GMDN Expert Team and with the explicit cooperation of the manufacturer.

10.4 GMDN new term Request

If an appropriate compatible generic device group (preferred term) for the identification/registration of a product cannot be found, a GMDN Request for a new term or a modification to an existing term can be submitted. This is done by going to the GMDN website homepage and selecting *Request a New Code*.


GMDN Home Page
About GMDN
Membership
FAQ
Information
Bulletins
Contact Us
Logout
English
Select Language
G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
Welcome to the New GMDN Code Request System
We have replaced the old manual code request form with a modern electronic system.
The new system offers a number of new benefits.
All new code requests must be paid for in advance.
If you have pre purchased code requests these will show in the "Requests Balance" on the main request a code page.
In this case you can complete your New Code Request and your request will be submitted and your balance adjusted automatically.
If you have not pre paid you can pay for your New Code Request after completion of the form via WorldPay by following the instructions on the screen.
If you wish to complete your New Code Request and to pay for it later or to arrange for your Accounts department to process the payment you can save your completed term and as soon as payment is received your term will be submitted to the expert team for processing.
You can track the progress of your request by logging on to the system and to viewing the request in the list presented by clicking on the request a code tab.
Throughout the process you will be kept informed of the progress via email.
The system will allow you to append files and pictures to the request.
The expert dealing with your request may require additional information from you. This will be requested by email and details of all messages will be available through the website.
The system will allow you to save a Draft version of your request if you do not have all the required information available you can save the form as a draft and re-open it at a later date to complete it. In this circumstance the request will not be processed until it is finished and submitted.
Existing Requests Record
Proceed New Request

Note: A shortcut to *Request a New Code* can also be found on the GMDN website homepage.


Actions
I would like to become a member of GMDN
Continue
I would like to submit a proposal for a GMDN code
Continue
I would like to learn about the GMDN
Continue
I would like to contact the GMDN Agency
Continue
I would like a free copy of the GMDN User Guidance
Continue

Further description can be found in the *GMDN Agency New Term Request Step-by-Step Guide*.

11. Obsolete Preferred Terms

Requirements and processes for retiring a GMDN preferred term.

All nomenclature systems must be dynamic; this means that they must, if and when necessary, be adjusted to reflect the current situation. Therefore, with all nomenclature systems, there are factors that create situations where it is necessary to remove (make obsolete) preferred terms from an active status. These factors are as follows:

Historical data – most nomenclatures have a historical background, i.e., they are based on earlier systems, methodologies, or in the case of the GMDN, a project involving the merger of six established terminologies. Obviously, in doing this, it is inevitable that some duplication and inclusion of ambiguous terms would result, and as the GMDN is maintained these anomalies would be discovered and corrected (i.e., a duplicated or ambiguous preferred term would be removed).

Technology – As technology expands the number and variety of medical devices, so too must a nomenclature expand to make accommodation. For example, ***Screw, bone*** would have been an appropriate preferred term for all orthopaedic bone screws for some period. However, with the introduction of an absorbable bone screw, it becomes apparent that the single term ***Screw, bone*** described as being made of metal, no longer holds good. Therefore two new GMDN preferred terms must be made, one for the metal or non-absorbable types, ***Bone screw, non-absorbable*** and a second for the new absorbable material types ***Bone screw, absorbable***. The old term ***Screw, bone*** now becomes ambiguous and has to be made obsolete.

Socio-environmental factors – Political and cultural changes in a society as well as the emergence and discovery of new diseases and disorders impact a medical device nomenclature. For example, the advent of HIV and its effect on blood related products, concerns related to infection from animal-derived products, and the recognition of latex-derived product allergies are all issues that may promote the revamp of certain sections of the GMDN to maintain currency. Such changes frequently result in the need to remove preferred terms and create replacements.

Understanding that a preferred term has been used in good faith to represent a product in many records and databases, the GMDN has a system for making preferred terms obsolete that does not create a disruptive situation for the GMDN user.

The procedure is as follows:

- When a preferred term is retired, a series of automated processes will happen.

- A fixed text phrase will supersede the terms definition, explaining that this preferred term has been made obsolete.

This text phrase is:

> This GMDN preferred term has been made obsolete and the code must not be newly applied to a device/product from the date it was made obsolete. If this preferred term code was applied to a device/product before the date it was made obsolete, it may continue to be used for the life of this unchanged device/product. For device/product identification starting from the date this term was made obsolete, please use the referenced, other, or new/improved GMDN preferred term code(s).

The GMDN experts will point to new possible replacement preferred terms. However, the user must check the appropriateness of the selections for their particular use.

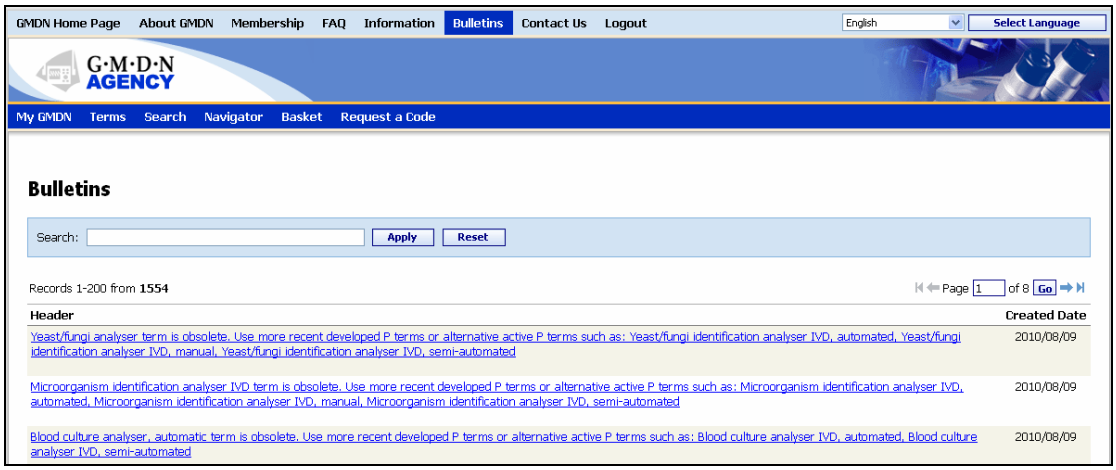
11.1 Bulletin board

When the preferred term has been made obsolete, it will be automatically pasted to the GMDN Bulletins.

If the User maintains their GMDN membership and uses the facilities of the GMDN database, then they will be informed of any term that they have in *My Terms* being made obsolete, via an automated email.

The standard text phrase conveys that if a device/product has been identified and registered (e.g., with an authority) using the code of the preferred term that has since been made obsolete, the identification of the device/product via that GMDN code is valid as long as the device/product remains unchanged. If the intended use or technology of the device/product changes then a new GMDN code would be required.

EXAMPLE of the Bulletin Board:


GMDN Home Page
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G·M·D·N AGENCY
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Terms
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Request a Code
Bulletins
Search:
Apply
Reset
Records 1-200 from 1554
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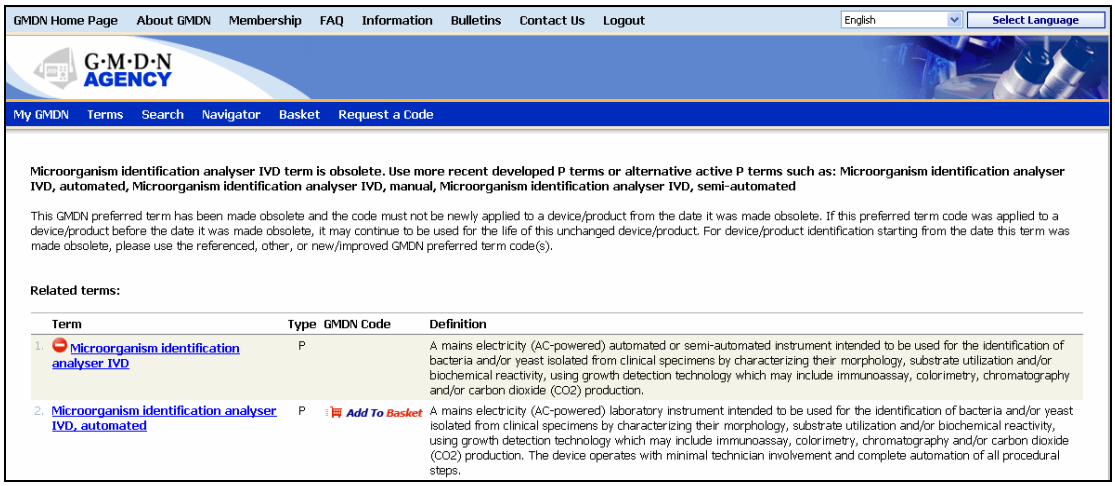
Header
Created Date
Yeast/fungi analyser term is obsolete. Use more recent developed P terms or alternative active P terms such as: Yeast/fungi identification analyser IVD, automated, Yeast/fungi identification analyser IVD, manual, Yeast/fungi identification analyser IVD, semi-automated
2010/08/09
Microorganism identification analyser IVD term is obsolete. Use more recent developed P terms or alternative active P terms such as: Microorganism identification analyser IVD, automated, Microorganism identification analyser IVD, manual, Microorganism identification analyser IVD, semi-automated
2010/08/09
Blood culture analyser, automatic term is obsolete. Use more recent developed P terms or alternative active P terms such as: Blood culture analyser IVD, automated, Blood culture analyser IVD, semi-automated
2010/08/09

By clicking on any of the term names (this is the preferred term that has been made obsolete) in the list of hyperlinked term names this will expand the view to display the definition.


GMDN Home Page
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G·M·D·N AGENCY
My GMDN
Terms
Search
Navigator
Basket
Request a Code
Microorganism identification analyser IVD term is obsolete. Use more recent developed P terms or alternative active P terms such as: Microorganism identification analyser IVD, automated, Microorganism identification analyser IVD, manual, Microorganism identification analyser IVD, semi-automated
This GMDN preferred term has been made obsolete and the code must not be newly applied to a device/product from the date it was made obsolete. If this preferred term code was applied to a device/product before the date it was made obsolete, it may continue to be used for the life of this unchanged device/product. For device/product identification starting from the date this term was made obsolete, please use the referenced, other, or new/improved GMDN preferred term code(s).
Related terms:
Term
Type
GMDN Code
Definition
1. Microorganism identification analyser IVD
P
A mains electricity (AC-powered) automated or semi-automated instrument intended to be used for the identification of bacteria and/or yeast isolated from clinical specimens by characterizing their morphology, substrate utilization and/or biochemical reactivity, using growth detection technology which may include immunoassay, colorimetry, chromatography and/or carbon dioxide (CO2) production.
2. Microorganism identification analyser IVD, automated
P
Add To Basket
A mains electricity (AC-powered) laboratory instrument intended to be used for the identification of bacteria and/or yeast isolated from clinical specimens by characterizing their morphology, substrate utilization and/or biochemical reactivity, using growth detection technology which may include immunoassay, colorimetry, chromatography and/or carbon dioxide (CO2) production. The device operates with minimal technician involvement and complete automation of all procedural steps.

The stop icon indicates that this is a term that has been made obsolete, whilst the term(s) displayed below it are the preferred terms that the GMDN expert is suggesting may be appropriate substitute terms. This is, however, only a suggestion as the user must make the final decision if this is applicable to the product in question.

12. GMDN Glossary

Terminology used to reference the GMDN is provided below as taken, in part, from the standard ISO 15225 *Nomenclature – Medical device nomenclature data structure.*

base concept: The broadest representation of the generic device group, and the primary listing basis of the GMDN. [Source: GMDN Maintenance Agency]

character: A member of a set of elements used for the organization, control or representation of data [ISO/IEC 8859-1:1998].

code: A system of alpha, alphanumeric, or numeric characters and rules by which information is represented and/or communicated.

collective term: A descriptor used to aggregate generic device groups by common feature or characteristic (e.g., may be a high-level device term or attribute).

concept: A unit of thought constituted through abstraction on the basis of properties common to a set of objects [ISO 1087:2000].

custom made device: Any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for sole use of a particular patient.

definition: A formal concise statement of the meaning of a preferred, template, or collective term.

device category: The broadest grouping within the nomenclature.

device intended for clinical investigation: A device intended for use in a designed and planned systematic study involving human subjects to verify device safety and/or performance.

device type: The identification of a manufacturer's specific product (i.e., make and model).

file: A named set of records stored or processed as a unit [ISO/IEC 2382-1:1993].

generic device group: (or Preferred Term) is the name given to any device which is thus generically identified together with others having the same or similar intended use and/or common technology.

GMDN (Global Medical Device Nomenclature): A nomenclature based on the structure of an international standard used to name, define, and code medical device products for data exchange between competent authorities

and others, exchange of post-market vigilance information, research, medical record keeping, e-commerce and inventory purposes.

identifier: One or more characters used to identify or name a data element and possibly to indicate certain properties of that data element [ISO 2382-4:1987].

maintenance agency: Organization representing the interests of regulatory agencies, manufacturers and healthcare providers to ensure the continued relevance and effectiveness of the GMDN.

manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under its own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

medical device/device: Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment of alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception;
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

multiple-linked synonym: An alternative name for a preferred or template term linked to more than one preferred or template term; it is used to enter and navigate the nomenclature and may or may not actually be synonymous with the term to which it is linked. [Source: GMDN Maintenance Agency]

name: Designation of an object by a linguistic expression [ISO 1087:1990].

nomenclature: System of terms which is elaborated according to pre-established naming rules [ISO 1087:1990].

preferred term: The name established to describe devices (or a device) having the same or similar intended use or commonality of technology.

product specifier: A marker used to indicate whether a term can and cannot be used for product identification. [Source: GMDN Maintenance Agency]

relational structure: A structure of data that are arranged as relations [ISO/IEC 2382-17:1996].

synonym term: An alternative name for a preferred or template term; it is used to enter and navigate the nomenclature and may or may not actually be synonymous with the term to which it is linked. [Source: GMDN Maintenance Agency].

template term: A general device name used to create a simple hierarchy for lexically-related preferred terms.

term: Designation of a defined concept in a special language by a linguistic expression [ISO 1087:1990].

13. GMDN Term Specificity Indication

The following table shows a non-exhaustive list of qualifiers that are used to make a preferred term more specific. These may be part of the term itself or be embedded in the term definition, or both.

Term	Definition
Animal-derived	Devices made from or containing a substance that is manufactured from animal tissue/body fluid
Antimicrobial	Devices containing an agent/substance to combat the growth of microorganisms
Automatic	Devices able to activate, move, and regulate itself
Battery-powered	Devices that are powered/operated by batteries – usually internal
Combination	Devices using two combined integral technologies or clinical functions
Drug-eluting	Devices containing a drug or drug coating that is slowly released into the body.
Electrically-powered	Devices that are powered/operated by a source of electrical power
Electronic	Electrically-powered devices that use electronics as opposed to mechanical means to function
External	Devices used on the exterior of the body
General-purpose	Devices are not designed with a particular special purpose and can be used for several of many purposes
Guayule-latex	Devices made from guayule natural rubber latex (NRL)
Hevea-latex	Devices made from Hevea natural rubber latex (NRL)
Human-derived	Devices made from or containing a substance that is manufactured from human tissue/body fluid
Hydraulically-powered	Devices that are powered/operated by a source of pressurized oil
Implantable	Devices implanted inside the body – usually to remain there
Indwelling	Devices resident within a bodily organ or passage, especially to promote drainage
Internal	Devices used inside the body – usually implantable
Intraoperative	Devices used during, or in the middle of a procedure (e.g., a surgical procedure), as opposed to before or after a procedure
Manual	Devices that are powered/operated by human hand/body power
Mechanical	Devices that use only mechanical means to function
Medicated	Devices containing a medication/drug
Multi-purpose	Devices that can provide many different clinical functions or take many different readings as opposed to one or two

Term	Definition
Non-latex	Device not containing latex
Non-powered	Devices that have no inherent power source
Percutaneous	Devices effected or performed through the skin
Pneumatically-powered	Devices that are powered/operated by a source of pressurized gas
Powered	Devices that are powered by some means other than by hand
Programmable	Devices that can be set to various programmes
Refurbished	Reusable devices that have previously been used on patients, and that have been subjected to additional processing and manufacturing for the purpose of additional uses on patients
Reprocessed	Single-use devices that have previously been used on a patient, and that have been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient
Reusable	Devices used more than once after disinfection/sterilization
Self-applied	The use of a medical device upon one's own body
Short-term	Device normally intended for continuous use for not more that 30 days
Single-patient	Used for one patient only
Single-use	Device used only once, then disposed of